PRESSURE ULCER: PREVALENCE, INCIDENCE, RISK FACTORS, AND THE PREDICTIVE VALIDITY OF THE BRADEN Q AND THE GLAMORGAN RISK ASSESSMENT SCALES IN PAEDIATRICS

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"The first step in the risk management process is to acknowledge the reality of risk. Denial is a common tactic that substitutes deliberate ignorance for thoughtful planning."

Charles Tremper, Professor of Law and Psychology, USA

DEDICATION

''Who doesn't thanks people doesn't thank God''

All praise and thanks are due to our merciful guide, **ALLAH***, who gave me the strength to go through this long journey of hard work, tiredness, fears, and waits.*

Thank you for giving me ***Hope*** *and* ***belief*** *in my abilities to complete what I started with patients, with tenacity and determination.*

Thanks again and again for giving me all of my loved ones, who supported me all the way:

My Mum

Your love and care was the candle in my darkest days, and my safeguard against my fears

My Husband

My soul-mate ***Ahmad****... I was lost for words when I started writing this... thanks for treating me like a loving father holding his little girl's hand to help her cross the road.*

My little Daughters

Sadeen*, 5 years,* ***Rahaf****, 2 years, and* ***Hala****, 10 months*

Big Sorry my angels... for letting your childhood days pass while I'm here and not here at the same time!!

My supportive sisters and brother...and my bigger beloved family

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This work is specifically dedicated for my beloved dears, who left my life early before I reached where I am; my dad, and my young sister; Abeer. I believe you are there watching me now with a smile!

And finally... this work is dedicated to ***All Children*** *who suffer illness and pain, rather than living happily and safe...*

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ABSTRACT

- ***Background:*** There is a paucity of research related to the problem of pressure ulcer in paediatrics. Variable incidence and prevalence rates have been reported, although, critically ill paediatric patients have proved to be at higher risk than those in general wards. Few investigations of contributing factors have been based on rigorous methods, and most existing risk assessment scales are either adult-based or depend simply on experience or observation.
- ***Objectives:*** Two separate studies were conducted as part of this research. A prevalence study aimed to measure the prevalence, location and categories of pressure ulcer, as well as pressure ulcer patients' characteristics in general inpatient paediatric wards. An incidence study was set up to measure the incidence, most affected locations, and categories of pressure ulcer, as well as significant risk factors for pressure ulcer development in critically ill children and neonates. It also aimed to compare the predictive validity of the Braden Q and the Glamorgan RASs in critical care areas.
- ***Design:*** One point prevalence study with a descriptive cross-sectional design and one observational cohort incidence study with longitudinal prospective design were conducted.
- ***Setting:*** All paediatric in-patient wards for the prevalence survey, and four paediatric critical care units (PICU, NICU, GIMU, and GICU) were surveyed in one university-affiliated hospital in Jordan. Paediatric patients in burn, isolation, and psychiatric wards were excluded**.**
- ***Sample:*** A total of 107 paediatric patients aged from birth up to 18 years old for the prevalence survey, and a total of 212 critically ill paediatric patients without pre- existing pressure ulcer for the incidence study, were recruited.
- ***Methods:*** All patients who met the inclusion criteria were included and assessed for pressure ulcer existence in one day for the prevalence study. Patients eligible for the incidence study were observed up to three times a week for two weeks, then once a week until critical care unit discharge, death, or when the eight week follow-up period ended. In both studies, data was collected by the primary investigator.

- ***Main Results:*** All identified pressure ulcers in both studies were categorised according to the European Pressure Ulcer Advisory Panel classification system. Eight patients (7.5%) had 13 PUs in the prevalence study and, of these, the majority were inpatients in critical units (87.5%, n= 7), had device-related ulcers (75%, n= 6), were female (62.5%, n= 5), younger than one year old (62.5%, n= 5), and had experienced longer stays hospital than pressure ulcer -free patients (Median (IQR)= 11 (27) vs. 4 (7)). Most of the ulcers seen were of partial thickness (category *I* and *II*) (n=6, 75%), while only two patients developed category *III* ulcers (25%), and none had category *IV* ulcers. If category *I* PUs were excluded, this would result in a prevalence rate of 2.8% (n= 3). The sites most frequently affected by pressure ulcer were the face (38.5%, n= 5), followed by the occiput and 'neck and shoulders', each with 15.3% prevalence (n=2).
  In the incidence study, 19 patients (9%) developed 29 ulcers, and as low as 5.2% when category *I* ulcers were excluded. Forty one per cent of pressure ulcers were category *I*, 48.3% category *II*, while only 10.3% were category *III* and none were category *IV*. The 'chest and shoulders' were the most affected areas with ulcers (20.7%, n= 6), followed by areas labelled 'other' (which included the arms, back and buttocks, as well as ears) (17.2%, n= 5), and four ulcers were located in each of the mouth, nose, 'feet and ankles' areas concurrently (13.8% for each). Based on a multivariate analysis, significant predictors of pressure ulcer were shown to be the *mobility* sub-item of the Glamorgan scale, and *being on mechanical ventilation for 4 days or longer*. The Glamorgan scale was more sensitive yet less specific than the Braden Q scale; however, neither of the scales was superior to the other in terms of its predictive validity.
- ***Conclusion:*** Pressure ulcers do exist in Jordanian paediatric patients, and with higher rates among those who are critically ill, thus would have its impact on changing the practice of Jordanian nurses to prevent or reduce its occurrence. Critical care unit paediatric patients most at risk include those who are supported on mechanical ventilation for longer periods, and those who are immobile. Both the Glamorgan and the Braden Q risk scales are valid tools to predict pressure ulcer among critically ill children, but neither is clearly superior to the other.

- ***Key words:*** Paediatric, Pressure Ulcer, Incidence, Prevalence, Risk Assessment, Risk Factors, Glamorgan, Braden Q, Risk Scale, Predictive Validity.

ABBREVIATIONS

ABGs	……..	Arterial Blood Gases
AUC	……..	Area Under the Curve
BP	……..	Blood Pressure
C°	……..	Celsius Degrees
CI	……..	Confidence Interval
CF	……..	Consent Form
CPAP	……..	Continuous Positive Airway Pressure
CRP	……..	C Reactive Protein
d.f	……..	Degree of Freedom
DV (s)	……..	Dependant variable (s)
E		the population effect size
ECMO	……..	Extracorporeal Membrane Oxygenation
EPUAP	……..	European Pressure Ulcer Advisory Panel
f ratio	……..	False Alarms Ratio
GCS	……..	Glasgow Coma Scale
GICU	……..	General Intensive Care Unit
GIMU	……..	General Intermediate Unit
HFOV	……..	High Frequency Oscillatory Ventilation
ICU(s)	……..	Intensive Care Unit (s)
IQR	……..	Inter Quartile Range
IV (s)	……..	Independent Variable (s)
K	……..	Serum Potassium Level
Kg (s)	……..	Kilogram (s)

LOS	……..	Length Of Stay
LR	……..	Logistic Regression
MAP	……..	Mean Arterial Pressure
MV	……..	Mechanical Ventilation
N	……..	Sample Size
n	……..	Number of cases
Na	……..	Serum Sodium Level
NG tube	……..	Nasogastric Tube
NICU	……..	Neonatal Intensive Care Unit
NPV	……..	Negative Predictive Value
NPO	……..	Nothing per Oss/ nothing by mouth
NPUAP	……..	National Pressure Ulcer Advisory Panel
NSRAS	……..	The Neonatal Skin Risk Assessment Scale
OR	……..	*Odd Ratio*
OR	……..	Operation Room
PEEP	……..	Positive End Expiratory Pressure
PICU	……..	Paediatric Intensive Care Unit
PIS	……..	Participant Information Sheet
PPV	……..	Positive Predictive Value
PRISM score	……..	Paediatric Risk of Mortality Score
PU (s)	……..	Pressure Ulcer (s)
RAS (s)	……..	Risk Assessment Scale (s)
RCT (s)	……..	Randomised Clinical Trial (s)
RF (s)	……..	Risk Factor (s)

ROC	……..	Receiver Operating Characteristics
SDT	……..	Signal Detection Theory
Sig.	……..	Significance
SpO2	……..	Oxygen Saturation
SPSS	……..	Statistical Package for Social Sciences
t- test	……..	*Independent Samples t- test*
U	……..	Mann- Whitney test value
χ^2 test	……..	*Chi Square test*
WOCN	……..	Wound and Ostomy Care Nurse

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CHAPTER ONE:

INTRODUCTION

1.1 A GLANCE AT THE CHAPTER

This chapter highlights the main inquiry of this research work, framing the main problem of concern, and showing its trends and significance. Also, it shows the main objectives of the current work, its context and structure.

1.2 AN OVERVIEW OF THE PROBLEM

Pressure ulcer (PU) is the main concern of this thesis, particularly in paediatrics. There is an abundance of data about PU in adults (Quigley and Curley, 1996), yet a paucity of research in paediatric care (Butler, 2007), despite numerous works showing that PUs exist in children, especially those who cared for in critical care areas such as intensive care units (ICUs) (Baharestani and Ratliff, 2007). To understand this problem reasonably, there should be a comprehensible picture of the size of PU problem, the factors that lead to its development and the characteristics of infants and children that predispose them to its formation (Butler, 2007), in addition to proper risk assessment to detect its occurrence. The lack of such information in the studied population initiated the current work.

Accurate description of ulcers, the predisposing factors, and clear documentation of its features is crucial for a proper prevention and management of this problem; hence, assessment was the major focus in this work.

For the current work, PU in particular was discussed in terms of its prevalence in the paediatric general population, its incidence and contributing factors in critically ill children, as well as comparing two risk scales which are currently in use in paediatrics, to show their abilities to predict children and infants' risk for PU' formation.

The assessment of PU is thus the main goal of this research. Assessment was noted as a significant aspect in many disciplines, such as engineering, food industry, environment, as well as medical field and nursing. To assess any problem of concern is the preliminary step for further actions, to prevent or intervene correctly. PU risk assessment is the same.

To establish a reliable prevention and management protocol for PU in patients, predefined assessment strategies should be initiated (Parnham, 2012). No proper intervention can be commenced without having enough information about the problem characteristics and the predisposing factors for its occurrence (Sims and McDonald, 2003).

PU inquiry in paediatrics was chosen specifically because of the emerging significance of the problem in terms of its size, contributing factors, duration and (high) financial cost, as well as its devastating effects on children's physical and psychological health and wellbeing, especially in teenagers. The urgent need for research on this subject, indicated by the paucity of identified literature regarding it, is compounded in the case of Jordan, the location of this study.

In the setting of inquiry, which is representative of the general status in Jordanian hospitals, no paediatric risk assessment strategies have been adopted, and no specific paediatric risk assessment scales (RASs) have been used; hence all applied interventions and prevention procedures, if existent, are based on nurses' personal judgment or individual efforts.

The abovementioned motivating factors thus inspired the current work, in addition to the researcher's own interest in PU problems in general, as gained from previous clinical experience as an ICU nurse, such as experience with patients suffering from ulcers, and the time and effort needed to treat them.

1.3 STATEMENT OF THE RESEARCH PROBLEM

Pressure ulcer in children and infants remains a relatively unexplored phenomenon for clinical nurses; this because of the general perception that PU is an adult, not a paediatric issue. A limited number of studies have investigated this problem, and a limited number of these employed a credible research design and produced reliable results. In addition, there is a dearth of evidence of PU contributing factors in paediatrics, either in infants or in older children (Barnes, 2004).

Risk assessment scales that have been used previously in paediatrics' settings were of limited predictive abilities, have no established reliability, or have indefinite credibility (Kottner et al., 2011).

It is necessary for nurses to have a recognised process of assessment, or a reliable tool to be used to measure children' risk for PU efficiently, rather than to base clinical

decisions on their own subjective opinion and experience, which predispose children to the hazards of misclassification of risk (Ayello and Braden, 2002).

Furthermore, a clear picture of the true factors that increase patients' risk of PU development need to be established. On one hand, ignoring risk factors would increases children' suffering and risk to develop PUs, while considering all suspected factors as risk factors, would consume high expenses by applying unnecessary intervention tools or prevention measures (Willock and Maylor, 2004).

1.4 RESEARCH AIM

The main aim of this research is to estimate the size of PU problem in a paediatric population in Jordan, while also considering the contributing factors of PU development, specifically in critically ill children. The predictive validity of two major paediatrics' RASs will be also compared while conducting the incidence part. All these are established to have a clear picture of the paediatrics' PU in the Jordanian population as a different data set to validate two appearing promising risk tools.

1.5 RESEARCH TERMINOLOGY

These are the definitions of the repeatedly used terms in this thesis wok, some based on specific criteria, while others were mentioned as meant by the researcher.

- **Pressure Ulcer (PU):** 'a localised area of skin damage with or without the underlying tissue, usually on the bony prominences, as a result of pressure, shear forces, or both'(EPUAP and NPUAP, 2009).

- **Pressure Ulcer Classification System:** staging/grading of identified pressure ulcer, from category I (non-blanchable redness) to category IV (full thickness tissue loss). In this thesis, the term 'category' was used to show stage/grade of ulcers as recommended by the EPUAP and NPUAP guidelines (EPUAP and NPUAP, 2009).

- **Skin Breakdown:** other types of skin damage that affect its intactness, but do not result from pressure, friction or shear forces, such as tape burns, skin tears and incontinence dermatitis (EPUAP and NPUAP, 2009).

- **Risk Assessment Scale (RAS):** a measure to identify individuals at risk who need preventive procedures, their type of risk, and the contributing factors that put these individuals at risk (Ayello and Braden, 2002).

- **Paediatrics:** this term was used to refer to all children and neonates, who aged from birth (whatever the gestational age at birth) up to 18 years old. **Neonates** referred to those who aged from birth up to one month old, while **children** referred to those aged from one month up to 18 years old.

- The whole **thesis** work was referred to as **'research'** or '**research work'**, while **'study/ survey/ audit'** referred to each separate part of the research; the incidence and the prevalence studies.

1.6 BACKGROUND TO THE RESEARCH PROBLEM

1.6.1 The scope of the problem

There is an emerging awareness of PU as a problem that affects the paediatric population, especially in those who are critically ill or with debilitating conditions (Baharestani and Ratliff, 2007). However, there is still a paucity of empirical evidence upon which new guidelines for the clinical area can be established (Cockett, 2002). Children and neonates have unique characteristics, based on their variant developmental milestones; which necessitates a specified protocol of skin care.

To have a proper intervention and prevention procedures, there should be a proper assessment, hence assessment is the preliminary step toward suitable prevention (Pallija et al., 1999, Willock et al., 2000); however, little is known about paediatric risk assessment, or the contributing factors for PU development in this population (Loman, 2000).

Pressure ulcers in children, as in adults, have many devastating negative effects, such as pain, lengthy hospital stay (McCord et al., 2004, Pallija et al., 1999), and disfigurement or permanent alopecia, which may affect the child's body image and cause embarrassment (Gershan and Esterly, 1993, McCord et al., 2004, Willock and Maylor, 2004). Any interruptions in a child's skin, either by medical devices, incontinence, wound or therapies, may cause them to be susceptible to infection (Noonan et al., 2006), and PUs themselves can become infected (Brook, 2004). In severe cases, such infections can lead to osteomyelitis (Bar-On et al., 2002, Willock and Maylor, 2004).

Pallija et al. (1999) found that paediatric PU patients are at more risk to have disturbed body image, anxiety and depression, especially adolescents, because of their increased concerns about their appearance, in addition to their beliefs that skin problems are an indicator of poor health prognosis.

Furthermore, PU was identified to be a financial burden both on health organizations and on individual patients, while being time- and effort-consuming as well (McCord et al., 2004). Because of all these psychosocial, social and economic consequences on

children, families and communities, there is a belief that preventing PU occurrence is much better than treating them after they occur (Quigley and Curley, 1996).

1.6.2 The size of the problem

Incidence and prevalence rates are two epidemiological terms used to calculate the size of any existing condition or a problem either over a specified time period, or at one point of time (Shields and Twycross, 2003). In paediatrics, the PU prevalence was found to range between 0.47-27.7% for this specific group (Willock et al., 2000, Baldwin, 2002, Suddaby et al., 2005, McLane et al., 2004, Schluer et al., 2009), while incidence rate varied between 0.25% and 32.8% (Waterlow, 1997, Curley et al., 2003a, Murdoch, 2002, Dixon and Ratliff, 2005, Willock et al., 2000, Baldwin, 2002, Huffines and Logsdon, 1997).

Although there is no agreement about the size of the problem, there is evidence that critically ill children are more likely to have PU than child patients among the general paediatric' population (Willock and Maylor, 2004, Murdoch, 2002, McCord et al., 2004, McLane et al., 2004, Suddaby et al., 2005, Cockett, 2002).

Regardless of the studied population of paediatrics, from the previously mentioned incidence and prevalence rates, it is manifest that children do suffer of PU, and in some cases with relatively high percentages. Detailed data about incidence and prevalence studies will be presented later in the literature review chapter.

1.6.3 The financial impact of the problem

There are several studies predicting the cost of this problem in adults, but not many mentioned for paediatrics. The average cost of the care of inpatient child with a primary diagnosis related to any skin problem has been found to be around $1,375 in one hospital in the USA; the children hospital of medical centre of Akron (CHMCA) in 1995. However, this is lower than the cost of PU specific treatment for the adult population, which was calculated by Lancellot (1996) as around $10,000-60,000 per ulcer (Pallija et al., 1999). In the UK, the treatment cost of category *I* PUs is around £1064, and £10,551 for category *IV*, while the total cost in the UK amounts to around

£1.4-2.1 billion annually (Bennett et al., 2004). These figures demonstrate the high compound cost of treating PU in many health organisations; yet, specific paediatrics related studies are needed to calculate the cost of PU treatment in this population.

1.7 SIGNIFICANCE OF THE STUDY

As explained previously, PUs do have negative impacts on patients' health and wellbeing, as well as being costly either on financial' or human' resources. All of this make a huge burden on the health organisation to protect their patients from undesirable hazards, while controlling expenses at the same time (McCord et al., 2004).

Thus, this thesis aims to discuss the PU problem, from size and assessment perspectives, to generate a clearer understanding about this condition in paediatrics, and more specifically in those who are critically ill. Literature about PUs in children and neonates are scarce, and existing studies generally lack empirical evidence, or have a descriptive nature (Willock et al., 2000).

Researchers believe that incidence and prevalence studies are necessary to establish benchmarking data about PU (Noonan et al., 2011, McLane et al., 2004). Others argued how using prospective incidence studies would help in exploring the performance of paediatrics RASs in certain populations (Barnes, 2004).

Having well established empirical evidence of the size of PU problem, and the related characteristics of ulcers, their most common locations, numbers, and classifications, as well as the contributing factors of PU in children would certainly help in improving and qualifying the existing prevention and interventions protocols, or even developing new prevention policies (Butler, 2007, Willock et al., 2009).

Moreover, testing the available paediatrics RASs would help in approving their reliability and predictive ability; a highly reliable and predictive tool is important to detect patients at risk. However, there are still doubts about the actual effect of using even a valid and reliable risk assessment tool in the reduction of the PU incidence rate in the clinical practice (Anthony et al., 2009, Kottner et al., 2011).

On the other hand, Ayello and Braden (2002) discussed the effect of neglecting to use a specific RAS in PU reporting, in which scenario only high risk patients would be reported and would consequently receive the prevention aids. The authors observed that using a formal risk assessment would help in identifying low and moderate risk patients, and hence would improve the consistency of applying interventions for patients in all risk group classifications.

Furthermore, Cockett (1998) described how using a specific RAS in one PICU had enabled the early identification of PU risk patients, and increased nurses' awareness of PU risk, in addition to the engendering the improved usage of preventive measures in a more consistent and timely manner, as well as improving the quality of documenting and describing ulcers. Highly specific tools help in implementing justified prevention procedures, and optimizing the use of nurses' time, effort and costs.

To-date, there is scant evidence to prove the validity and reliability of any of the paediatric' RASs on all paediatric populations. For example, the Braden Q scale was devised to be a valid tool for paediatrics, yet it was not proved valid on neonates aged under 21 days old, nor for older children aged over eight (Noonan et al., 2011). In this thesis, these age groups of children and neonates will be included in testing the Braden Q RAS predictive validity.

In brief, identifying the true PU risks to patients and the risk factors that lead to PU development in paediatrics would help in reducing the pain and suffering of patients, as well as in improving the quality of life of chronically ill children. In addition, it would decrease the negative consequences such as infection, sepsis, surgical intervening, and even depression and embarrassment (Pickersgill, 1997, Brook, 2004).

1.8 CONTEXT OF THE STUDY

The research was conducted in one major setting in Jordan. It was divided into two separate studies: study one, the prevalence study, and study two, the incidence and risk factors. This was done to simplify the exposition of the thesis different areas. Each part of the study has a different study design and research method, and a different sample.

The prevalence study was conducted through a cross-sectional point prevalence design, with a sample of all hospital wards of inpatient children and neonates. In contrast, the incidence study was a prospective observational cohort audit, with the sample being critically ill children and neonates. However, both parts of the study were direct audits, consisting of direct skin assessment of children, and recording their characteristics, or suspected contributing factors, as detailed later in the data collection tool.

Moreover, collecting the risk factors and comparing the predictive validity of the two used paediatrics scales (the Glamorgan and the Braden Q scales) was implemented through the incidence part, because of the nature of the desired outcome, which will be discussed in later chapters. Despite the fact that there are two separate studies in this thesis, each deals with the same problem of interest, which is PU in paediatrics.

The prevalence study was intended to be conducted contemporaneously with the incidence study, because of lacking any data about PU in the Jordanian paediatric population. Prevalence was the initial step from which an estimate of the size of the problem in Jordan was addressed. Later, the data extracted from the prevalence study facilitated choosing the area of interest; the critical care units, where the incidence study was accomplish; since the vast majority of PU cases in paediatrics were identified in these units.

1.9 STRUCTURE OF THE THESIS

This thesis was written up within six chapters, as outlined in (figure 1.1), each of which chapters have sections and subsections. Each starts with an overview of the chapter, and concludes with a summary of the chapter's content. This structure aimed to ease the reader's smooth transition and follow-up of presented data. The thesis chapters are:

Chapter One, the Introduction: constructed to give a brief overview of the whole work of the thesis, the main aims of the study, the measure of inquiry, its size and significance in clinical sector.

Chapter Two, the Literature Review: contains a critical analysis and elucidation of the identified previous literature, and its relatedness to the main themes of this thesis,

which are the prevalence and incidence, and the risk assessment. The risk assessment themes contained both the risk factors and the paediatrics risk scales. Also, this chapter sheds light on the strengths and weaknesses of relevant previous researches, and identifies the existing gaps. The applied theoretical framework was also discussed.

Chapter Three, the Methodology: explains the research methods used in each part of the thesis, with justifications applied for each commenced strategy used throughout the thesis, and the data collection process.

Chapter Four, the Results: presents the main findings of the study, within its two separate studies. Also, the incidence study was discussed through three major sub-sections: the incidence rate, the risk factors, and the predictive validity of the two utilised scales.

Chapter Five, the Discussion: elaborates on the major findings of the two studies in this thesis, extrapolated from the results chapter, with a thorough discussion of the findings in relation to the thesis main questions, hypotheses and objectives. Also, the theoretical framework concerning the results is demonstrated.

Chapter Six, the Conclusion: summarizes the main findings, including strengths, limitations, and the implications for various practice fields, while illustrating the unique contributions of this work to current knowledge.

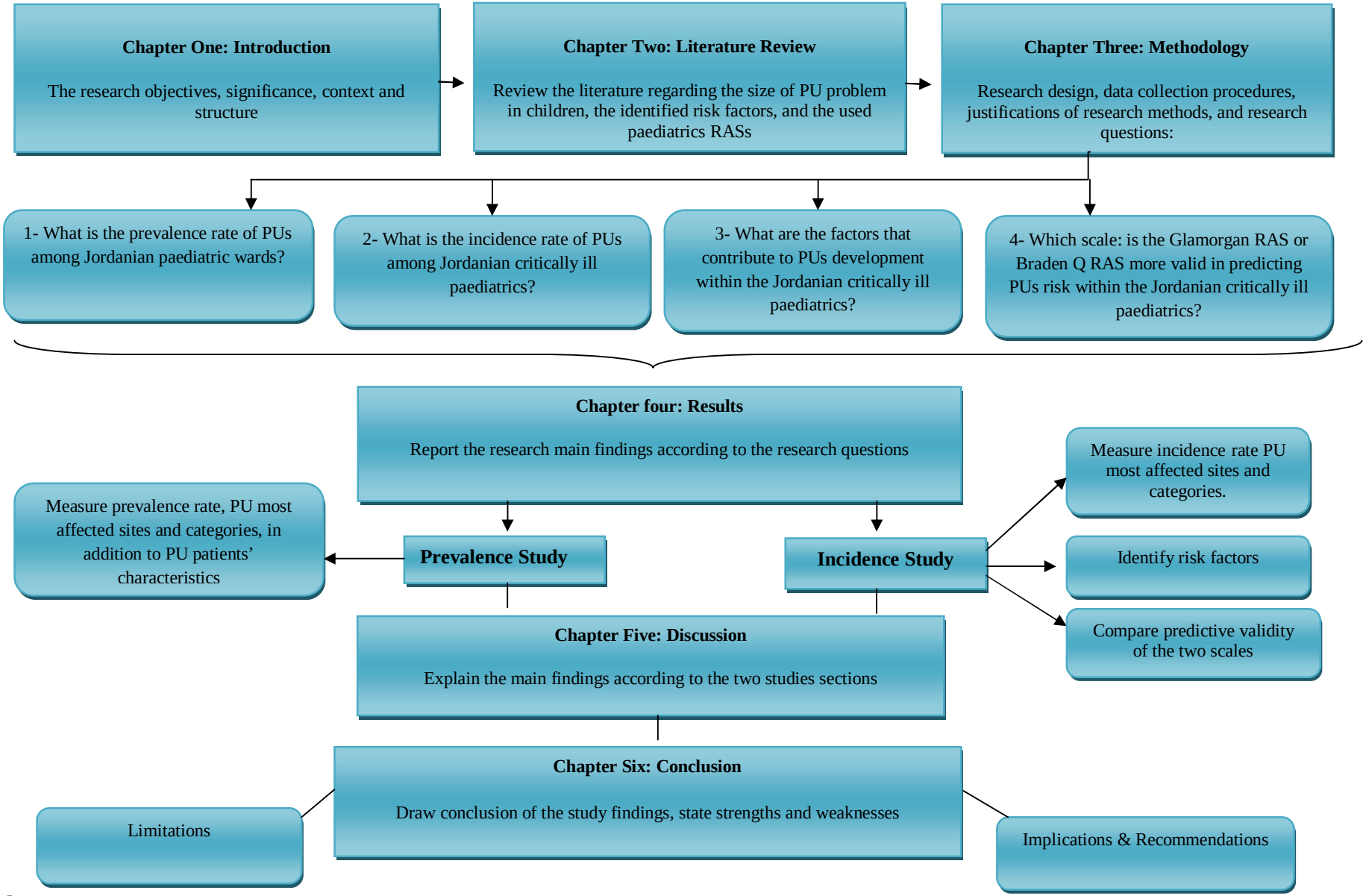

Figure 1.1: Overview of the Thesis Structure

1.10 **SUMMARY**

This chapter has introduced the research problem, the main aims and the objectives. The background of PU problems in paediatrics has been elucidated, while considering the size of the problem in this particular population, either through incidence or prevalence surveys. Also, the financial cost of PU borne by health organizations, as well as the negative consequences on the child's health and wellbeing, was addressed.

The major sections and trends of the thesis have been discussed, giving justification of the research designs used in both studies research designs. The thesis chapters and structure was summarised, with a brief description of each, to help in formulating a preamble understanding of the flow of the following thesis chapters.

CHAPTER TWO:

LITERATURE REVIEW

2.1 A GLANCE AT THE CHAPTER

This chapter reviews previous literature on the problem of interest in the current research work. Firstly, the size of the PU problem in paediatrics in general is underlined by investigating the available incidence and prevalence surveys. Moreover, studies are highlighted which deal specifically with critically ill paediatric patients, and the risk of PU in this particular population, as well as in general paediatric patients is explored. Next, the paediatric RASs currently in use are investigated, with focus on the Glamorgan and Braden Q scales in particular. Finally, a description of the theoretical framework used is also provided with an explanation of how it guides the whole research process.

2.2 SEARCH STRATEGIES

The literature review process began with an attempt to identify resources related to the main themes of this thesis, namely the incidence and prevalence of PU in paediatrics, and risk assessment for children who are critically ill. Subsequently, the previously identified risk factors of PU were investigated and the performance of the two paediatric RASs, the Braden Q and the Glamorgan, were compared. A number of electronic databases were searched to locate the relevant literature, either through the *De Montfort University'* (DMU) library services, or via other identified databases, such as *Science Direct*, using the Athens service.

The databases searched via the DMU website were the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the MEDLINE, the British Nursing Index (BNI), the Applied Social Sciences Index and Abstracts (ASSIA) and the Cochrane Database for Systematic Reviews (CDSR). In addition, an e-mail alert service offered via the 'Google Scholar' website was made use of. This facilitated the early identification of newly published literature related to the main enquiry of this research, allowing the researcher to remain up to date with current work.

Searches within the databases named above were conducted using specific terms and key words, which are listed in appendix (1.1). Having a list of terms or key words enabled the researcher to focus the search within the scope of the current work, preserving time and effort. Also, it helped prevent any articles related to the main research enquiry being inadvertently missed.

In addition, a number of data resources were accessed which could not be located by searching conventional databases. These were conference reports, theses, and some official websites, such as those of the European Pressure Ulcer Advisory Panel (EPUAP) and the National Pressure Ulcer Advisory Panel (NPUAP). Finally, the reference list of each identified research paper was searched manually to locate any relevant papers which may have been overlooked.

2.2.1 Inclusion Criteria

- Because of the limited amount of relevant literature available, all material published at any time prior to the end of the research period in March 2013 was considered to be potentially suitable.
- The studies which informed the incidence and prevalence surveys had to have used a reliable research method.
- All studies related to paediatric PU risk assessment scales.
- All studies related to risk factors for PU formation in paediatric populations.
- Being in English language.

2.2.2 Exclusion Criteria

- Studies in languages other than English.
- Studies with samples which included non-paediatric subjects, i.e. those over 18 years old.
- Studies specifically related to other types of skin problems in paediatrics, such as diaper dermatitis or IV extravasations.
- Studies that were found not to be related to the inquiry of the current research, after the filtering process was implemented, which will be mentioned later.
- Studies which discussed PU management methods, since prevention and management protocols were not within the scope of the current research.
- Researches based on personal experience or own opinion, without having a proper research methods, or reliable outcomes.

2.2.3 Filtering Procedures

- Any study deemed to be irrelevant on reading its title was eliminated.
- For studies with titles which appeared relevant, the abstracts were read; if relevant, the papers were reserved.
- The studies with relevant abstracts were read in full; if the main body of the research met the inclusion criteria and was relevant to the main enquiry of the current study, then it was reserved.

In relation to the main themes adopted, there was a thorough investigation and assessment of the target data, since all studies which informed in the incidence and prevalence surveys were required to have a calculated percentage of the size of the PU problem in a paediatric-only population. For the risk assessment component, all identified contributing factors and characteristics were taken into consideration if they came from studies which had well-defined methodological approaches and clearly stated results. All identified paediatric-only PU RASs were analysed, with the main focus being on the scales used in this study, the Glamorgan and the Braden Q.

Because of the limited amount of paediatric PU literature available, all studies that met the inclusion criteria and made it through the filtering process were included. The whole process and the number of hits is summarised in the figure below:

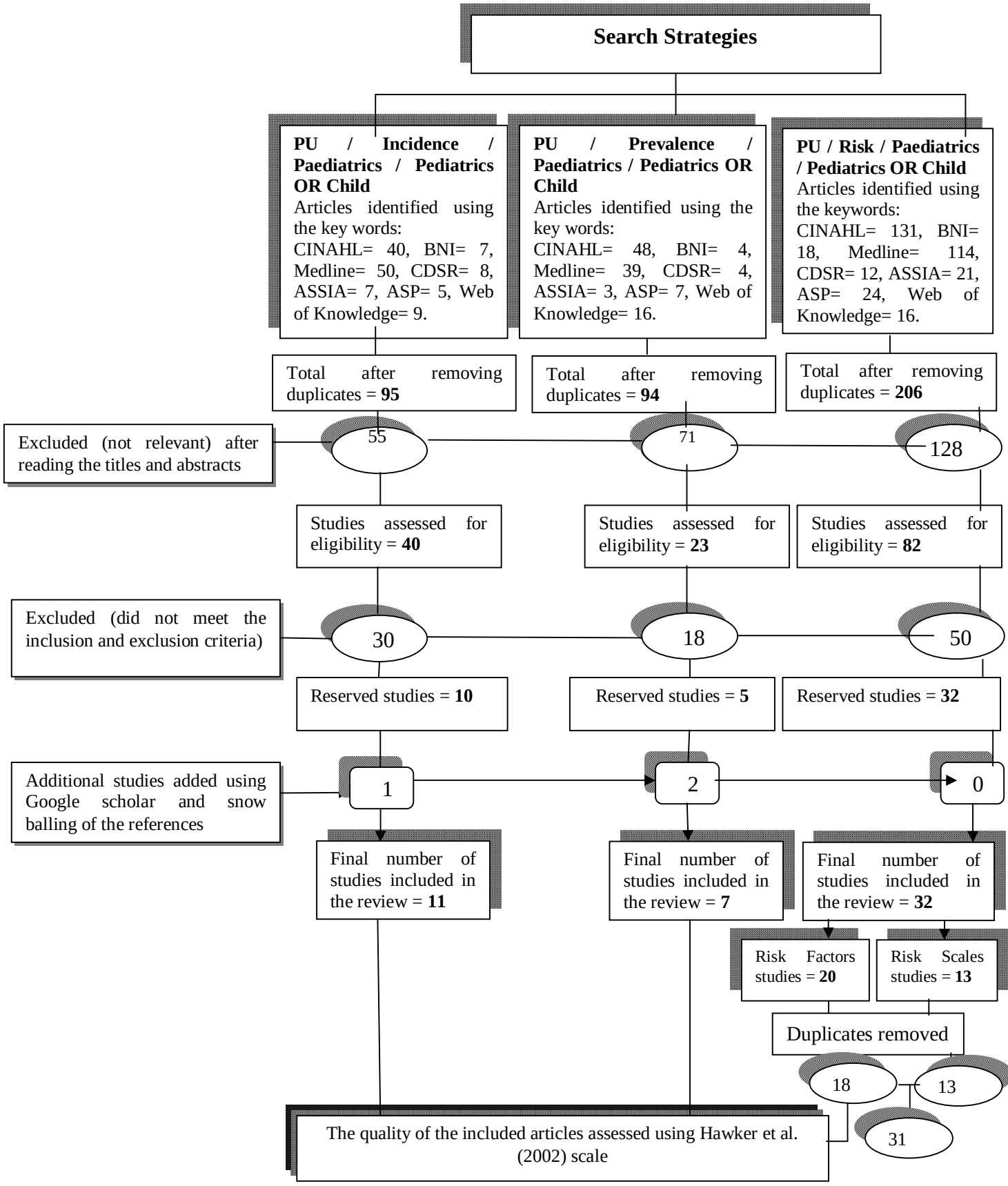

Figure 2.1: Search Strategies

2.2.4 The Evolution of Literature Search

There is a paucity of research on PU in paediatrics compared to that of adults; for this reason most of the literature found which related to children was included in this study. Moreover, in Jordan particularly, there have only been a scant number of PU studies, and none related to the paediatric population.

Some difficulty was encountered in trying to address the main themes of this study with the existing literature at the beginning of the search process. However, the number of related studies has recently increased, enhancing the literature review as new incidence and prevalence studies were identified. For other issues such as comparing the performance of the two scales, the Glamorgan and Braden Q, however, there was not a large amount of supporting literature. Only two papers were identified, one of them a retrospective (Anthony et al., 2010) and the other a poster abstract (Long et al., 2011).

As regards the risk assessment theme, all paediatric RASs were mentioned and discussed briefly, although the major focus was on the scales used in the data collection process of this research. Also, many risk factors were discussed in reference to the available paediatric PU studies, despite the fact that many of these studies had a cross-sectional research design. Some difficulties were encountered while discussing some of the paediatric literature in which the PU problem was combined with other types of skin conditions, or in which some categories of PU were treated as other types of skin breakdown, such as redness.

It was not possible to exclude such studies, however, because of their importance, because their description of the skin breakdown is much like that of PU, or because universal PU classification systems were used to describe the categories of these breakdowns.

All the research publications consulted were entered into ‘EndNote’, a reference management programme (EndNote, 2008), which was used to simplify the process of sorting and storing references. It also helped with removing duplicated references, as well as with adding citations and formulating the whole thesis’ reference list.

The whole process of searching for relevant literature was started in 2010, long before the actual writing process commenced. However, further articles were identified, and the search for newly published studies was maintained, as the research proceeded between April 2010 and March 2013.

Finally, all incidence and prevalence studies which have been included in the literature review of this thesis were evaluated for their quality based on the tool developed by Hawker et al. (2002) (Appendix 1.2) although, in fact, any tool that can be used to evaluate the quality of empirical studies included in any literature synthesis would have been adequate, because there is none which is universally recommended.

Hawker et al.'s (2002) tool was developed to describe different methods used to systematically review a piece of research from different angles. It includes 9 areas to be evaluated, starting with title and abstract, going through introduction and aims, different methodological issues, and ending with the usefulness and applicability of the study. Each aspect of the evaluated research is awarded a score from 4 (good) to 1 (very poor). The criteria upon which each study must be evaluated are mentioned in the tool.

All incidence and prevalence studies accepted for the current review were assessed using this tool to ensure the adequacy of all their elements. However, most of the studies of paediatric PU identified here were limited in the details provided in terms of their aims, samples, methodology, or were inadequate in other areas. Therefore, in many cases the evaluation was limited to what was reported.

2.3 OVERVIEW OF PRESSURE ULCERS (PU)

2.3.1 The skin:

The skin is an important part of the human body. As a result of its importance in protecting against the external environment, keeping body configuration and a good body image, it is thought to represent the first line of the body's defence against external hazards (Pallija et al., 1999, Pasek et al., 2008). Also, skin is

important in assessing maturity in paediatric patients in general and in neonates in particular since skin composes around 13% of a neonate's weight compared with 3% of a typical adult's (Huffines and Logsdon, 1997).

Skin is composed mainly of two layers: the epidermis and the dermis. The epidermis is the most outer layer and consists of dead cells which are shed and replaced continuously. The dermis, on the other hand, consists of skin cells which contain blood vessels and capillaries, sweat glands and nerve endings. If these layers of the skin are exposed to continuous pressure, tissue ischemia and necrosis may occur. Also, if left untreated, deeper tissue such as muscles and bones might be affected (Hagelgans, 1993). Many clinical practices in neonatal units affect the intactness and normal functioning of babies' skin, which plays a significant role in their risk of morbidity and mortality (Huffines and Logsdon, 1997).

Moreover, this organ is affected by environmental changes, such as the level of moisture, temperature and friction or shear forces, which can lead to serious conditions and diseases. One of these is PU.

2.3.2 Pathophysiology of Ulcer Formation:

The way PU develops is still not clear. Authors believe that ulceration is related in some way to insufficient blood supply to the skin. Pressure on the outer skin in turn puts pressure on blood capillaries, resulting in decreased blood flow, diminished supply of nutrients and oxygenation, as well as the accumulation of metabolic waste, which causes cell hypoxia, tissue necrosis and ulcer formation (Brook, 2004).

However, it has been argued recently that the mechanisms which lead to PU formation is composed of four major processes that affects three functional units which are the cells, interstitial spaces, and the blood capillaries. The four processes include local ischemia to the tissues, tissue injury from the reperfusion effects, the impairment in the lymphatic fluid flow, and more the resulted permanent cell deformity (Nixon et al., 2005). Furthermore, there are external

forces affects these four processes which are pressure, shear forces, and a mix of microclimate related factors such as moisture and temperature which can affect the cells wellbeing and hence its tolerance to the other forces.

Anyhow, the pressure forces was thought to be the major component of the whole PU occurrence process; since this factor is always presented when the shear forces occurs, and its duration and intensity would in some manner affect the skin tissue tolerance (Defloor, 1999). So, a sustained unrelieved pressure (intensive and for longer time periods), with or without a combination with the other external forces would lead to PU development.

The micro capillary pressure that is needed to cause reduction in blood supply was assessed by Landis (1930) cited in (Quigley and Curley, 1996), who found that 32 mmHg is the closing pressure of arterial limbs of capillaries in adults. If applied pressure exceeds this limit, the capillaries would close, and blood supply would be reduced or obstructed, resulting in PU development. However, no equivalent study on children has been undertaken, and the upper limit of pressure in adults may not be a safe threshold for children and infants, since the degree of pressure an adult's skin can tolerate is not the same as in children because of their different physiological conditions and states of maturity (Quigley and Curley, 1996).

2.4 **PRESSURE ULCERS IN PAEDIATRICS: PREVALENCE AND INCIDENCE**

Prevalence and incidence are two concepts used in epidemiology. They are employed to measure the size of some event at a specific point of time, or during a specified time period (Shields and Twycross, 2003). 'Point prevalence' has been defined as: "measuring the proportion of all cases of a condition among a population, considered at risk for developing that condition at one point of time" (Groeneveld et al., 2004b, P. 109). 'Incidence' was defined by Craig et al. (2002) cited in (Willock and Maylor, 2004, P. 56) as: "the number of new cases occurring in a defined population over a specified period of time''.

These two concepts are being increasingly utilized in health care disciplines, including nursing. In the field of PU, pressure ulcer prevalence can be understood to be the number of patients who have pressure ulcers within a group of assessed patients at one point in time (Willock and Maylor, 2004). Most PU prevalence studies have been carried out over one day (Willock et al., 2000, Schluer et al., 2009, Noonan et al., 2006, McLane et al., 2004, Dixon and Ratliff, 2005) but they can be done over a longer period of time. On the other hand, PU incidence is defined as "the number of people who develop pressure ulcers in a specific population over a specified period of time" (Willock and Maylor, 2004, P. 56).

Data collected through incidence studies can be comparable within the same area of interest. By calculating the incidence rate, an event's occurrence can be compared between different populations, whatever the size of those populations (Shields and Twycross, 2003). On the other hand, prevalence studies can measure an event only at a particular point in time (Shields and Twycross, 2003), thus the size of any problem might differ within the same population in different settings, or in different time periods, according to the studied sample at that particular time.

Both prevalence and incidence of PU are significant indicators of patients' quality of care. This is because, hospitals usually estimate the size of a problem in a specific population by conducting periodical prevalence and incidence studies (McLane et al., 2004) and skin breakdown, PU, and many other skin issues are crucial indicators of the quality of nursing care provided for patients in many health organisations (Suddaby et al., 2005, Noonan et al., 2011, Noonan et al., 2006, McLane et al., 2004). Moreover, Cockett (2002), in a review of research, concluded that skin care was an integral part of each act of applied nursing care.

What is more, incidence can be used to evaluate the efficiency of the utilised risk assessment scales, and the benefits of their use in different paediatric populations, as well as to estimate the size of PU problems. This is usually done by testing the scale's ability to detect PU risk in a specific population (Barnes, 2004, Kottner et al., 2011). Also, prevalence studies are thought to have the effect of limiting the negative

consequences of PU among children, by increasing the nurses' awareness of the problem, and related prevention methods (McLane et al., 2004).

Although PU is one of the conditions that is often measured in hospitals by prevalence and incidence surveys, few studies have addressed the size of the PU problem in paediatrics. Even the studies which are available mostly have limited generalisability to specific populations, inadequate sample sizes, or unclear methodology (Sims and McDonald, 2003, Cockett, 2002).

2.4.1 Paediatric Pressure Ulcer Prevalence

Willock et al. (2000) measured both the prevalence and incidence of PU in paediatrics through two separate surveys with a gap of one month in-between. The prevalence rate, based on a sample of 183 children and neonates from one hospital's paediatric wards, was 6.5% (n= 12) while the incidence rate was 7.2% (n= 6), based on a sample of 82 children and neonates in the PICU, orthopaedic, and neurosurgical wards. In addition to the small sample size of these studies, the prevalence rate dropped to only 2.1% (n= 4), and the incidence to 3.6% (n=3), when blanchable erythema was excluded from calculations. In other words, including this type of erythema inflated the actual size of the problem in this population.

Baldwin (2002) also tried to estimate the size of the PU problem in children aged from birth up to 21 years old, by conducting a mail survey which consulted 234 members of four paediatric health care databases in the USA. The data provided by the members was used to estimate the incidence and prevalence of PU in this population. Of 4429 paediatric inpatients in hospitals in 1998, 21 developed PU, giving a prevalence of 0.47%, while incidence rate was 0.29%, since 337 patients developed PU, out of 115,870 newly admitted patients for the same year.

However, Baldwin's (2002) study has several drawbacks in terms of the reliability and generalisability of its findings. Firstly there was a low response rate, as only 25% of questionnaires were returned. Also, the study design might have led to under-reporting of the actual size of the problem, since it depended on nurses' willingness and time to respond correctly to questionnaires. Moreover, target

hospitals were those with website addresses, but several hospitals could not be accessed via the web, and this may have caused the exclusion of many potentially affected children from the survey. Next, data collected by means other than direct assessments of patients' skin, might have under- or over-estimated the actual size of the problem.

One multi-site study (McLane et al., 2004) also reported a considerably low prevalence rate of 4% (n= 43). Although this study had a large sample size (n= 1064), covering a range of ages from neonates to children up to 17 years old, the fact that some paediatric groups, such as burn patients, or those who were physiologically unstable, were excluded might limit the generalisability of the findings. The authors recommended the use of an incidence study to collect benchmarking data about PU concurrently with the prevalence study.

Other prevalence studies have also been conducted in specific hospitals at multiple points in time (Dixon and Ratliff, 2005, Suddaby et al., 2005), yet the way in which they estimated the size of the problem was different. Dixon and Ratliff (2005) surveyed five paediatric inpatients units (PICU, NICU, two general acute care units, and a rehabilitation unit), to estimate the prevalence rate of PU in one hospital over two years. In the first survey, two of 77 patients had PU, giving a prevalence rate of 3%; one year later, the prevalence was 4% (n= 3 out of 79 inpatients). Although Dixon and Ratliff measured PU in children of various ages, from birth up to 21 years old, their study's small sample size might limit the usefulness of the results. Also, investigating the size of the problem in these specific units might have over- or under-estimated the size of the problem if compared with other paediatric wards.

Suddaby et al.'s (2005) five quarterly prevalence surveys of four paediatric inpatient units (PICU, medical-surgical, oncology and adolescent units) revealed a much higher prevalence rate of 23% (n= 80). However, the authors included other types of skin breakdown, such as diaper dermatitis, as category *I* injuries, which might have inflated the rate.

A significantly low PU prevalence rate was also reported in Noonan et al. (2006), where just four patients out of a total 252 were found to have PU (1.6%), Nonetheless, this rate increased when device-related ulcers were included (6.7%, n= 17). Nie (Nie, 2008) reported a PU prevalence of 10.7% among 266 children in one hospital (n= 22). However, this was a short paper, in which prevalence was calculated only for medical-surgical and ICU paediatric patients, which could have affected the representativeness of the sample. In addition, the absence of descriptions of affected areas and prevalent categories of ulcers, and incomplete explanations of findings might limit the study's comparability with other similar prevalence studies.

The highest PU prevalence rate reported in the literature was the result of a multi-site study by Schluer et al. (2009), in which 43 of 155 inpatients had PU (27.7%). The vast majority of ulcers found were device-related, which might have contributed to the high prevalence of category *I* ulcers. Excluding this category would reduce the prevalence to only 4.5% (n= 7), which is similar to that observed in previous relevant studies.

A summary of all identified paediatric prevalence studies presented in (Appendix 1.3).

2.4.2 Paediatric Pressure Ulcer Incidence

Incidence rates were noticed to be higher than the prevalence rates in some studies, especially when conducted in high risk populations, such as among children and neonates in critical care units (Huffines and Logsdon, 1997, Curley et al., 2003a, Zollo et al., 1996). An incidence of 16.9% (n= 10) of occipital PU was reported for paediatric patients who had survived open heart surgery (Neidig et al., 1989) but this rate fell sharply, to only 4.8%, after certain protocols to prevent such types of ulcers had been implemented. However, this study was retrospective, depended on data from patients' charts, and had a limited sample size (n= 59) but, on the other hand, it was the only study that has aimed to estimate the size of the PU problem in cardiac paediatric patients.

One retrospective chart audit of 373 patients in a PICU (Schindler et al., 2007) reported almost the same incidence of 18% (n= 71). However, this study divided the incidence of skin injuries into three types: redness only (6.2%, n= 25), skin breakdown only (8.5%, n= 34), and skin breakdown with redness (3.2%, n= 13), using the NPUAP classification system. None of the children admitted to the PICU during the study period (15 weeks) were excluded, which might strengthen the generalisability of its findings to other PICU patients. Nevertheless, it's retrospective design, and the fact that it only included PICU patients might hinder it is findings regarding the actual size of the problem, and the reported risk factors.

A higher incidence rate was reported in one matched case control study (Zollo et al., 1996) of 271 patients in one PICU (26%, n= 65) over an 18 week period. However, this was retrospective study, which again might affect the reliability of findings, and, as in Willock et al. (2000), the inclusion of blanchable erythema might have inflated the actual incidence rate of this sample, since it dropped to only 7% (n= 20) when the category was excluded, along with non-blanchable erythema.

Curley et al. (2003a) also observed a high PU incidence in three PICUs, where 86 of 322 patients on bed-rest had developed PU (27%), although this rate would have been even higher if the figure had been combined with an additional 27 device-related ulcers. The prospective multi-site design of this study might strengthen its results, yet the sample's limited age range (21 days to 8 years old), and the fact that children with congenital cardiac diseases were excluded, might limit the generalisability of the findings to such groups of children and neonates.

In contrast, a lower incidence rate was reported in one early multi-site study (Waterlow, 1997), in which 17 out of 302 inpatients had developed PU (5.6%), although this low rate might be because the study population came from general wards rather than critical care units as in previously discussed studies. Furthermore, a much lower incidence rate was reported in one PICU (Murdoch, 2002), before and after the application of a certain type of mattresses, where the incidence improved from 0.9% (seven children developed ulcers out of 750) to 0.25% (two children developed ulcers out of 790) over two years period. However, these findings

accounted for deep tissue ulcerations (category *III* and *IV*) only, plus, the calculation of these rates was based on patients referred to the hospital tissue viability nurse, and thus, any case missed by the nurse would have affected the reported incidence.

Two previous studies have discussed PU incidence specifically in neonates (Huffines and Logsdon, 1997, Fujii et al., 2011). In the first study, six out of 32 patients in one NICU developed PU (19%), while, in a later multi-site study, 14 out of 81 children recruited from seven NICUs (16%) did so. Both studies had similar incidence rates despite the fact that Huffines and Logsdon (1997) was a pilot descriptive study with a small sample size, whereas Fujii et al. (2011) was a prospective multi-site audit, and with a much larger sample.

In summary, as has been seen, the variation in reported paediatric prevalence and incidence rates could be influenced by the inclusion of blanching erythema in PU categorisation (Willock et al., 2000, Zollo et al., 1996), In addition to the exclusion of non-blanchable erythema category in another study (Curley et al., 2003b) , which was done to avoid the overestimation of the actual incidence rate by nurses who misunderstand the actual description and classification of this category

Nurses can distinguish between category *I* PU, or non-blanchable erythema, according to the EPUAP (2009), and other types of hyperactive erythema of the skin, since the latter would usually disappear within at least half the duration of time required initially to cause the skin erythema (Loman, 2000).

Also, the use of different terms and definitions to refer to PU and other types of skin breakdown might be responsible for some of the variation in previous paediatric studies, since several studies included other skin conditions in their PU incidence and prevalence calculations (McLane et al., 2004, Zollo et al., 1996, Suddaby et al., 2005) whereas a few others did not consider redness to be PU (Schindler et al., 2007). Moreover, some studies considered pressure injuries resulting from medical equipment to be different from mobility-related PU (Noonan et al., 2006, Curley et al., 2003a).

A summary of all identified paediatric PU incidence studies are presented in (Appendix 1.4).

2.5 PRESSURE ULCER RISK ASSESSMENT: FACTORS AND SCALES

To gain a clear picture of any problem or phenomenon, the establishment of a good base to start from and to build on is crucial. The assessment of a problem is the initial step, upon which further steps, such as applying preventive actions, and developing management policies, are performed (Quigley and Curley, 1996).

Pressure Ulcer in paediatrics is a problem that needs to be clearly described, so that the health care provider can attempt to prevent its occurrence (Jones et al., 2001, Pickersgill, 1997). The prevention of PU is an important aspect of care for this population and is generally considered to be one of the quality indicators of the nursing care provided (Curley et al., 2003b, Schluer et al., 2009). Although nursing care cannot eliminate all of the contributing factors of PU development in children nurses still play a significant role in the early detection and management of these factors (Pallija et al., 1999).

Many measures to prevent PU are used in PICUs. However, none of these could be evaluated for its effectiveness, without there being sufficient knowledge of the patients' risk (Curley et al., 2003b, Zollo et al., 1996). Thus, to help in inhibiting the occurrence of PU, all factors which contribute to PU formation should be identified (Pallija et al., 1999, Pickersgill, 1997, Zollo et al., 1996). In other words, in order to understand the aetiology behind its development, nurses need to look beyond PU itself, and need to have a systematic risk assessment tool that can be used to detect PU risk in paediatric patients (Bedi, 1993).

PU risk factors have often been discussed in the literature with regard to adults, but this is not the case for children. The limited number of available studies that discuss paediatric PU risk factors has been commented on by many (Curley et al., 2003b,

Curley et al., 2003a, Schluer et al., 2009, Murdoch, 2002, Willock et al., 2000, Loman, 2000, Garvin, 1997).

The research designs of most paediatric risk studies can be said to have limitations. For example they may be descriptive (Willock et al., 2000, McLane et al., 2004, Murdoch, 2002, Waterlow, 1997, Willock et al., 2005b, Baldwin, 2002, Dixon and Ratliff, 2005), cross-sectional (Schluer et al., 2009, Suddaby et al., 2005), have used a retrospective protocol (Neidig et al., 1989, Samaniego, 2004, Schindler et al., 2007), have limited statistical analyses or unclear details (McCord et al., 2004, Zollo et al., 1996, Gordon, 2008), or have a small sample size (Willock et al., 2000, Huffines and Logsdon, 1997, Fujii et al., 2011, Manning and Curley, 2012). While some authors have used adult risk scales to predict PU in children (Schluer et al., 2009), a few others have used paediatric risk assessment scales which had no approved statistical validity (Loman, 2000, Huffines and Logsdon, 1997, Murdoch, 2002, McLane et al., 2004).

2.5.1 Pressure Ulcer Risk Factors in Paediatrics

2.5.1.1 Risk factor classifications

Risk factors related to PU development in children are usually classified in different categories or sections; sometimes they are linked with specific groups of children who have specific diseases, such as children with cardiac problems (Neidig et al., 1989), respiratory problems (Schindler et al., 2007), orthopaedic patients (Samaniego, 2004), premature babies (Fujii et al., 2011), and those with burns (Gordon, 2008).

In addition, Braden and Bergstrom (1989) divided PU risk factors into two major types: those which were caused by an increase in the intensity and duration of pressure, such as immobility or low sensation, and those which were caused by a reduction in patients' tolerance to pressure, such as nutrition and pain. Additionally, skin tolerance to pressure was divided into another two sub-types: intrinsic and extrinsic (Quigley and Curley, 1996).

Some factors such as immobility have its effect on increasing the pressure forces on patients' skin in vertical manner, while any existing shear forces at the same time would lead to horizontal forces on soft tissue, these both would resulted in intense and prolonged forces on the skin and hence PU formation (Defloor, 1999).

Pickersgill (1997) stated that intrinsic factors are those which arise as a result of the patients medical and physical conditions. Examples given in the literature are nutritional status, blood oxygenation and perfusion (Quigley and Curley, 1996) age, medical diagnosis, pain and medications (Murdoch, 2002).

According to Pickersgill (1997), extrinsic factors are those which are linked to the external environment, and might reduce the ability of patients' own skin to tolerate increased pressure, or its increased duration. Examples are increased friction and shear forces between the patient's skin and other surfaces or medical devices, and increased moisture of the skin caused by leakage, drains or incontinence, among others (Quigley and Curley, 1996). Both types of factors are clarified in table 2.1 below.

Table 2.1: The Intrinsic and Extrinsic Risk Factors for Pressure Ulcer

	Intrinsic	**Extrinsic**
Type of factor	- Nutrition. - Oxygenation and perfusion. - Age. - Medical diagnosis. - Pain. - Medications, such as vasopressors or sedation. - Immobility.	- Friction and shear of patient's skin with other surfaces, such as beds, casts, etc. - Medical equipment rubbing or pressing on patient's skin. - Moisture, from drainage for example.

2.5.1.2 RISK FACTORS IN PAEDIATRICS: BACKGROUND

There are few studies available about paediatric PU risk factors (McCord et al., 2004, Manning and Curley, 2012, Schindler et al., 2007). Murdoch (2002) suggested

using literature concerning adults as a preliminary base to identify risk factors in paediatrics while research is ongoing, because, according to Murdoch, most paediatric studies have depended on adult data. However, adult risk factors are not always applicable in paediatrics, because of children's distinctive anatomical, physiological and psychological features, which are different to those of adults (Murdoch, 2002, Bedi, 1993, Waterlow, 1997, Willock et al., 2000).

In infancy and early toddlerhood, the head is proportionally larger and heavier than the body trunk so these young children are at higher risk of developing occipital and ears PU while in a supine position (Willock et al., 2000, Neidig et al., 1989). As children get older, their bodies will begin to match the proportions of adults' bodies, and thus the affected sites, such as the sacrum, heels, and trochanter, become much the same as those seen in adult patients, (Murdoch, 2002).

This information might explain why Samaniego (2004) found that most of the ulcers seen in a group of orthopaedic PU patients were in the lower extremities, especially in the feet areas (50%, n= 25), since more than half of the patients were above the age of 10 years old (n= 29). The author believed that, as the children got older, or their neurological statuses deteriorated, they were at higher risk of sacral ulcers.

Furthermore, it is thought that, because infants and young children have limited hair growth, and less subcutaneous tissue in the occipital area compared with adults, this increases their risk of pressure and shearing forces in that area (Neidig et al., 1989).

Most of the studies of paediatric PU risk factors identified simply involved descriptions of patients' characteristics, without any significant correlations between the predicted factors and PU occurrence being inferred (Baldwin, 2002, Samaniego, 2004, Dixon and Ratliff, 2005, Waterlow, 1997, Willock et al., 2005b, Willock et al., 2000, McLane et al., 2004, Murdoch, 2002). A few more studies used statistical analyses to infer significant associations between contributing factors and PU development. However, most of these used questionable methodology since they were, for example, retrospective or cross-sectional (Schindler et al., 2007, Manning and Curley, 2012, Schluer et al., 2009, Suddaby et al., 2005), or depended on other

means to address risk factors (Gordon, 2008). Others used simple inferential analyses, such as the univariate tests, to reveal the risk factors in their paediatric populations, which are not as rigorous as the multivariate analyses (Willock et al., 2007, McCord et al., 2004, Neidig et al., 1989).

Curley et al. (2003a), Zollo et al. (1996) and Fujii et al. (2011) were the only studies identified which employed appropriate methods and advanced statistical analysis. However, it can be said that Zollo et al. and Fujii et al. did not provide enough details about the findings of some of the statistical tests.

a) Paediatric Risk in General Wards

Several studies have described the features of PU-patients in different paediatric wards. Waterlow (1997), for example, studied children aged from birth up to 16 years old, who had suffered from severe illnesses, lengthy surgeries, and had more devices attached to their skin such as splints, casts, or tubes than PU-free patients. She suggested that this group's increased risk of PU had resulted from a collection of extrinsic factors such as pressure, friction or shear forces, and moisture, although these findings did not achieve statistical significance.

Willcock et al. (2000) conducted a combined incidence and prevalence survey in general paediatric units but only included PICU, orthopaedics and neurosurgical units in the incidence study. The authors described a variety of characteristics which could be linked with PU formation in this population, namely being over- or under-weight, inadequate diet for the child's age, hemodynamic instability, oedema, dehydration, incontinence, or an abnormal skin condition. In addition, more than half of the PU-patients were noticed to be less aware of pain and pressure, and the majority suffered from impaired mobility. The patients also tended to be younger in age, particularly those who developed occipital PU.

Baldwin et al. (2002) also report younger children to be especially prone to PU, and mention medical devices such as tractions, as well as being sedated, hypotensive, suffering from sepsis, spinal cord injury or severe illness as features associated with PU- patients. However, due to problems associated with the mail survey design,

response rate, and the representativeness of the sample, this study is believed to be of limited value.

One further multi-site cross-sectional survey (McLane et al., 2004) found that children under 3 months old had a higher prevalence of PU occurrence. The PU patients also appeared more likely to be immobile, intubated, to suffer from severe illnesses, and to have had longer lengths of stay in the hospital. Despite the large sample recruited for this survey, however, none of these observations were supported by statistical evidence.

Young age was again correlated with PU in children in five quarterly cross-sectional surveys carried out (Suddaby et al., 2005). Affected children were also described to be smaller in weight, had more frequent episodes of diarrhoea, and were attached to more medical devices than those who were free of PU. These children also scored lower on the Starkid scale (this scale is discussed later on this section), although the scale's validity had not been previously tested. Moreover, these factors were also shown to be associated with other types of skin breakdown such as diaper dermatitis.

Willock et al. (2005b), in another multisite survey of eleven hospitals, collected data on 54 PU patients. The majority were found to have limited mobility, with more than half being completely immobile, and also suffered from impaired nutrition, low serum Albumin level, pain, and inappropriate self-care abilities for their age. However, the absence of a comparison group of PU-free patients prevented the authors from drawing any statistical relationships between these observed factors and PU development.

In another publication, Willock et al. (2007) combined data from previous incidence and prevalence surveys with multi-site data (Willock et al., 2005b, Willock et al., 2000) and were able to propose a significant link between children's restricted mobility, or any difficulty in changing position, with PU formation. In addition, persistent pyrexia, anaemia, prolonged surgery, and having equipment or surfaces pressing on the skin were noticed to be significantly related to PU occurrence in paediatrics. Having a larger sample size (n= 337), and lowering the significance

level ($p< 0.01$) might have reduced the chance of type *I* errors and enhanced the power of the results. However, the results were proved only by univariate analysis, and the study design was retrospective.

One further descriptive study (Dixon and Ratliff, 2005) named immobility as a typical characteristic of paediatric PU-patients, and also described these children as more likely to be critically ill, hypotensive, mechanically ventilated, oedematous, and to have had longer lengths of stay in hospital. However, despite the fact that these were presented as features of general paediatric patients, most were actually related to children cared for in critical care units. Moreover, no statistically significant relationship between any of these features and PU development was established.

One additional multi-site cross-sectional survey (Schluer et al., 2009) tested factors identified as being related to PU occurrence by both univariate and multivariate analyses. The significant factors were a low Braden score of risk (using a cut-off score of ≤ 20), along with characteristics related to the wards and institutions. Most identified ulcers were device- related, and PU-patients had longer stays in hospital than PU-free patients. However, the small sample size ($n= 155$) and the research design may limit the generalisability of these features, also, the used scale was argued before to be inappropriate for use in paediatric population (Kohr and Curley, 2009).

Two other studies discussed risk factors related to PU development but these were in specific paediatric populations (Samaniego, 2004, Gordon, 2008). Samaniego's study (2004) was a retrospective charts audit of PU patients who visited one wound clinic with orthopaedic- related illnesses, mainly Myelodysplasia, cerebral palsy, and clubfeet. The identified risk factors were paralysis, insensate areas, high activity, and immobility. However, these contributing factors were extracted from descriptive statistics only and based on a small group of PU-patients ($n= 50$), thus the study's findings may only relate to this particular population of children. One further study reported low activity as predictor of skin breakdown in neonates, yet this was not tested statistically (Huffines and Logsdon, 1997).

Gordon (2008) investigated risk factors of PU occurrence in paediatric burn patients. Several specific burn characteristics were agreed by 15 burn experts, using a modified Delphi technique, to be associated with PU development. These were total burned body surface area, number of splints, MAP < 60 mmhg for the past 24 hours, incontinence, calories intake, unburned area exposed to wetness and, as in previously mentioned literature, immobility was also related to PU occurrence in this population. However, because no actual audit was performed, and the identified factors were not tested statistically, in addition to the unique nature of burn-patients skin, these findings might be limited to this particular population of children.

b) Paediatric Risk in Critical Care Areas

Although different populations of children and neonates were reported to be at risk of PU formation (Willock et al., 2000, Samaniego, 2004, Pallija et al., 1999, Galvin and Curley, 2012), it is generally agreed that the risk of PU is higher among critically ill patients (Curley et al., 2003a, Willock et al., 2000, McCord et al., 2004, Neidig et al., 1989, Zollo et al., 1996) who have specific characteristics that predispose them to the higher risk. One prospective cohort study over 322 children in three PICUs in the USA (Curley et al., 2003a) found that the most important contributing factors for PU development in this group of patients were the use of mechanical ventilation (MV), being hypotensive (MAP< 50 mmhg), and having lower Braden Q scores (cut- off score ≤ 16).

Being on MV, or being intubated, is not a newly addressed risk factor for PU in this group of children and neonates, but has often been discussed in other research (Zollo et al., 1996, Fujii et al., 2011, Schindler et al., 2007, McLane et al., 2004, Dixon and Ratliff, 2005, Manning and Curley, 2012). Yet, the MV itself could be not the actual risk for these patients, but the fact that they would be immobilised for variant periods might contribute to their increased risk of PU formation.

It has sometimes been argued that it is the use of special settings on the ventilator, such as a high Positive End Expiratory Pressure (PEEP) level, or special types of ventilation, like High Frequency Oscillatory Ventilation (HFOV), which contribute

to PU formation, rather than the intubation itself (Curley et al., 2003a, McCord et al., 2004, Manning and Curley, 2012). McCord et al. (2004) found that using a level of PEEP as high as 10 cm of water, is usually associated with children who are unstable, or severely ill, which may mean that they are positioned less frequently by nurses, and hence their risk of PU is increased.

A few other studies discussed how spending longer periods on MV would increase the child's risk of PU formation (Zollo et al., 1996, Neidig et al., 1989, Curley et al., 2003a). For example, Neidig et al. (1989) observed that intubation for longer than 7 days was significantly related to PU development in children following open heart surgery, because these children are usually haemodynamically unstable, so nurses prefer not to perform positioning until they become more stable. In addition, there are other factors which restrict head repositioning for this population such as the presence of Jugular intravenous catheters, or head and neck oedema (Neidig et al., 1989).

Cardiovascular instability has been previously identified as a typical feature of patients affected with PU (Murdoch, 2002, Willock et al., 2000). Also, patients' general physical condition was found to be highly predictive of their risk of skin breakdown in one pilot study of neonates in ICU (Huffines and Logsdon, 1997).

Moreover, in Zollo et al. (1996), the mean length of ventilation for children with intact skin was around 4 days, compared with a mean of 7 days for patients with skin breakdown. However, multivariate analysis revealed only two significant risk factors, which were race and the Paediatrics Risk of Mortality Score (PRISM). Interestingly, this was the first and only study to highlight race as a risk factor for skin breakdown in paediatrics; however, the authors explained that this may have been due to an underestimation of category *I* and *II* ulcers in children with dark skin since redness may be difficult to detect in this population. The PRISM score, on the other hand, was also reported to be related to PU formation in children, and this score would reflect the acuity of the child's condition during their stay in ICU (Schindler et al., 2007).

Hypotension and treating patients with vasopressors and inotropes have also been discussed in the literature (Zollo et al., 1996, Curley et al., 2003a, Manning and Curley, 2012, Murdoch, 2002). Maklebust (1987) explained how patients with low blood pressure, on vasopressors, or who have a low cardiac output will compensate by shifting blood supply from the non-vital organs like the skin, to vital organs such as the heart or kidneys, for example. This could affect the proper response of the skin to any local compression, and ischemia (Curley et al., 2003a).

Critically ill children of a younger age have also been said to have a higher risk of PU development (Zollo et al., 1996, Neidig et al., 1989, Curley et al., 2003a, Schindler et al., 2007). Neidig et al. (1989), for example, found that children aged 36 months and younger were at higher risk of developing occipital PU following open heart surgery, and that all ten children who had developed occipital PU, out of a total 59 patients, were younger than 3 years old. The authors believed this was due to disproportionate size and weight of infants' and young children's heads compared with their bodies, as well as restricted mobility and positioning, their extremities being restrained to avoid self extubation, and sedation use. All together, these factors make the pressure more intense and prolonged (Neidig et al., 1989).

Sedation and neuromuscular blockers have been reported several times as being significantly related to PU development in critically ill paediatric patients (Zollo et al., 1996, Curley et al., 2003a). Such types of medications are thought to decrease the normal process of children's sensory perception and response to pain or pressure, which would diminish the body's natural protective reactions (Murdoch, 2002).

Willock et al. (2000) also noticed that children and infants had a significantly higher incidence of occipital PU development, especially those admitted to the PICU. All children in the incidence part of their study except for one had been admitted to PICU, and over a third of those who developed PUs in the prevalence study were inpatients in the PICU.

McCord et al. (2004) noted that the majority of identified PU cases had occurred in infants and children less than 3 years old (66%, n= 37) and another study, which was

developed to test a new neonatal skin RAS, found that the mean age of neonates who did develop skin breakdown was lower than that of the breakdown-free group (29.4 ± 2.6 vs. 33.9± 3.8) (Huffines and Logsdon, 1997).

A lengthy stay in hospital or in ICU has been named as a risk factor for PU development in acutely ill children (Zollo et al., 1996, Neidig et al., 1989, McCord et al., 2004, Schindler et al., 2007). McCord et al. (2004) speculate that increasing the LOS to more than 96 hours would usually be associated with longer periods of immobilization, poor nutrition and weight loss, especially since most of children admitted to the PICU would experience periods of NPO (Nothing per Os or nil by mouth) during their stay.

Furthermore, PICU LOS was found to be significantly related to occipital PU development in children following open heart surgery (Neidig et al., 1989). This was thought to be because a PICU stay of longer than 8 days is usually associated with longer periods of MV and intubation, longer periods of immobilization and limited positioning, which places children at higher risk of pressure on the occiput area. Also, shorter periods of ICU stays of 4 days and more were confirmed by both univariate and multivariate analyses as being significantly associated with PU occurrence in one PICU (Schindler et al., 2007).

Impaired nutrition and inadequate intake of calories were also found to be features of PU-patients (Willock et al., 2000, Gordon, 2008), yet these studies were descriptive, and did not focus on ICU patients in particular. Certain types of nutritional supply, such as Total Parenteral Nutrition (TPN) have been said to increase patients' risk of PU category *I* and above, (Curley et al., 2003a). Although Curley et al. (2003a) did not state how this could relate to an increased risk of PU; it could be explained in some way by the acute health condition of children who receive it, or the effect of pressure from the devices used with such type of nutrition, such as cannulas and tubes.

However, weight loss and malnourishment predispose children to the loss of subcutaneous tissues which increases the projection of bony prominences and hence

increases friction and shear, as well as pressure. Also, critically ill children would burn calories at a higher rate than children who are not as seriously ill (Murdoch, 2002).

In addition, smaller children or those who lose weight during their ICU admission are thought to have a higher incidence of PU formation (Fujii et al., 2011, McCord et al., 2004, Huffines and Logsdon, 1997). Willock et al (2000) also reported that excess weight could also increase children's risk of PU, perhaps because of the limited ability of overweight children to control their body position easily, especially when in acute care conditions.

Young children, especially neonates, were shown to be at an increased risk of developing PU as a result of their immature skin in a prospective multisite study of seven NICUs (Fujii et al., 2011) which discussed the effect of skin texture on neonatal vulnerability to PU. Neonates with skin texture scores 0 or 1 (using the Dubowitz neonatal maturation assessment scale), were at significantly higher risk of PU. The authors explained that children with immature skin would gain the lowest scores on the previously mentioned scale, where 0 indicates extremely thin and gelatine like skin and 1 represents skin that is very smooth and thin. Also, any child born at less than 33 weeks gestation was believed to be at higher risk of PU occurrence, due to the immature Dermoepidermal-junction of their skin.

There is agreement, however, that skin maturity in neonates is usually achieved within 3 weeks (21 days) of birth, irrespective of their gestational age at delivery (Fujii et al., 2011, Quigley and Curley, 1996, Curley et al., 2003a). Fujii et al. (2011) reported that 8 out of 13 neonates who developed PUs had been born at under 33 weeks gestation, and 11 ulcers out of 14 developed within the first 21 days of life.

Children and neonates were thought to be different in both their skin response and tolerance of pressure. Waterlow (1997), for instance, believed that neonates were more at risk of extravasations, bruising or torn skin caused by infusions, heel pricks or the strapping of tubes, as a result of their delicate immature skin. Consequently,

she recommended taking this difference into consideration while caring for neonates and very young children.

Neonates, and more specifically underdeveloped preterm babies, are believed to have several characteristics that affect their skin's normal barrier functions, and increase its risk of breakdown, these include; high skin permeability, which increases the absorption of chemicals and drugs as well as increasing heat and water loss (Curley et al., 2003a).

Fujii et al. (2011) discovered a number of other factors statistically related to PU occurrence, namely incubator humidity and temperature, limited repositioning, and the type of support surface used. However, all of these were extrapolated from the use of univariate analysis only, which might affect the strength of evidence provided, in addition to the fact that a small sample size was used (n= 81). Furthermore, all of these factors might be specific to this particular population of neonates. The increased risk of PU in patients cared for on special turning surfaces / beds, or the late initiation of positioning of patients was also supported by McCord et al. (2004).

Children cared for on special surfaces, such as low-air-loss beds were thought to have additional problems with increased friction and shear on the occiput, rather than having pressure relieved (McCord et al., 2004).The authors identified the lack of enough evidence of these beds efficacy in relieving or reducing pressure in paediatrics.

Furthermore, the attachment of medical devices, such as catheters, electrocardiogram (ECG) leads, splints, O2 saturation probes and nasal tubes, to patients' skin has been found to be significantly associated with PU occurrence in children and neonates (Fujii et al., 2011, Manning and Curley, 2012, Murdoch, 2002). Murdoch (2002) reported that one child developed severe ulcers as a result of being on a cervical board for more than 36 hours. Fujii et al. (2011) also describe endotracheal intubation as a risk factor for PU among NICU patients, yet the authors believe this is not due to hypoxemia or impaired oxygenation issues; rather, it results from the pressure of the nasal CPAP used on patients' skin.

Oedema has also been named as an added risk factor for PU development. This factor was reported once in relation to critically ill children (McCord et al., 2004), and on another two occasions for general paediatric patients (Willock et al., 2000, Dixon and Ratliff, 2005). Oedema is believed to increase the distance between the capillary beds and adjacent cells, which reduces the rate of diffusion of oxygen and nutrients to the affected area, and may impair the circulation and increase the risk of PU to that area (McCord et al., 2004). Head and neck oedema was also reported to be a feature that limited the head positioning in children following open heart surgery, and hence increased their risk of occipital PU occurrence (Neidig et al., 1989).

Other factors have been noted to be specific to some sub-sets of ICU patients. For example, there may be an increased risk of occipital PU risk in patients with ventricular septal heart defects following open heart surgery (Neidig et al., 1989). Although the significance of this factor might be skewed, as 76% of children with this condition were younger than 36 months old (13 out of 17 children), so the young age of these patients might be the actual basis of the risk, rather than the diagnosis itself. Furthermore, these patients would usually suffer from acute preoperative symptoms, such as failure to thrive and congestive heart failure, which require urgent surgical intervention, and it should be taken into consideration that around 29% of children in the whole sample had had this diagnosis (Neidig et al., 1989).

In Zollo et al.'s case control study (1996), prolonged surgery, and having a higher Paediatric Overall Performance Category (POPC) score were also documented as factors contributing to skin breakdown in PICU children, although how the POPC is scored, and how it performs in relation to PU, was not described in this study. It is known, however, that this scale was developed to measure the neurological abilities of paediatric patients, with a score range from 1 (normal) to 6 (brain death) (Fiser, 1992).

Additionally, a high score on the Ramsay scale was reported to be significantly associated with category *I* and above PU in another PICU population (Curley et al., 2003a). This score reflects the child's level of response ranging from 1

(restless/agitated) to 6 (no response to painful stimuli). The ratings of both of these scales might help demonstrate the effect of impaired neurological and sensory responses on PU risk in children, since this would entail a poor response to pain and pressure, and an unawareness of when to mobilise or change position, which would increase the risk of PU formation, as discussed earlier. A summary of identified paediatric PU risk factors studies is presented in (Appendix 1.5).

2.5.2 PAEDIATRIC RISK ASSESSMENT SCALES (RASS)

The first step in achieving successful prevention of any problem is performing a proper assessment (Zollo et al., 1996). To make a reliable assessment, there is a need for specific guidelines which enhance the assessment process. Such criteria or guidelines will help individual assessors to maintain objectivity, and ensure a systematic organized assessment process (Huffines and Logsdon, 1997).

Such criteria should also be accompanied by a comprehensive group of associative factors or causative factors, which should cover most of the problem's dimensions (Anthony et al., 2009). However, in practical terms, that is almost impossible. No criteria can include a huge number of factors and be easy to follow and use at the same time (Willock et al., 2009). For that reason, experts have developed specific tools that contain the most relevant and the most predictive risk factors. These are called 'risk assessment tools'.

A risk assessment tool or scale (RAS) is defined as an instrument which aims to identify patients who are at risk, and to determine their level as well as their type of risk (Willock et al., 2009).

The use of an appropriate, valid and reliable assessment tool for PU is recommended for paediatrics as well as for adults (Loman, 2000, Kottner et al., 2011, Zollo et al., 1996).This is said to be due to the unique characteristics of children, either developmentally or according to their physical and psychological response to pain (Garvin, 1997). Also, having a special paediatric RAS may play a role in standardizing the preventive and therapeutic actions of nurses, as well as helping

ensure that time consuming and costly preventive measures are properly allocated, only to those patients who are really in need of them (Zollo et al., 1996).

From another perspective, Some paediatrics RASs were designed to include assessing all variant age groups of paediatrics, while others were developed to be used only in a specific population of children, mostly the neonates. Few RASs were designed specifically for neonates (McLane et al., 2004, Huffines and Logsdon, 1997), and this because of the thoughts that this particular population has its own unique characteristics, that put them at a different level of PU risk. Neonates were argued before for example to have premature skin texture especially if were premature babies, that would lead them to lose water and absorb medications more rapidly than other paediatrics' age groups. This in its turn would result in increasing the microclimatic processes on the neonate's skin normal tolerance of pressure (Huffines and Logsdon, 1997, Fujii et al., 2011).

From another perspective, having one scale that fits to all paediatric age groups was discussed before to be necessary to score patients risk based on their different developmental milestones (Willock et al., 2007). It might be difficult as well as impractical to have several tools to measure risk for different age groups of paediatric patients.

In my own opinion, a predictive tool is that one which is easy to fill in and follow in practice, while at the same time is able to measure risk correctly on different age groups according to their variable developmental levels; this would in some degree preserve nurses' time and efforts.

Thirteen scales which have been devised to measure PU risk in paediatrics were identified. Four of these were established specifically for PICU populations (Bedi, 1993, Garvin, 1997, Cockett, 1998, Olding and PATTERSON, 1998b), two tools were developed for neonates (Huffines and Logsdon, 1997, McLane et al., 2004) and one for cardiac and general operation rooms (OR) (Galvin and Curley, 2012). The remaining scales were designed for general paediatric wards (Quigley and Curley,

1996, Pickersgill, 1997, Willock et al., 2007, Barnes, 2004, Suddaby et al., 2005, Waterlow, 1998).

Though RASs are not always perfect indicators of patients' risk of developing PU, they are thought to be useful in increasing bedside nurses' objectivity in assessing and identifying ulcers (Huffines and Logsdon, 1997). Also, these scales may help to conserve health care resources and save time and money, as well as to standardize nursing practice (Huffines and Logsdon, 1997, Barnes, 2004, Garvin, 1997). One study which tried to develop a paediatric PU RAS concluded that RASs are important because they are reminders for nurses of the patients who are at risk, and of the related risk factors. Also, they are a means of recording information related to PU existence, the care provided, and the required prevention and management procedures (Barnes, 2004).

Prospective design is thought to be crucial for validating RASs because the scales' risk scores work as predictors of PU occurrence (Kottner, 2011). For example, Barnes (2004) has recommended the application of an incidence study to test her newly developed paediatric RAS. Anthony et al. (2010) also recommended the use of prospective design to compare predictive validity between three paediatric RASs, the Glamorgan, Braden Q and Garvin .

Although it is generally agreed that paediatric patients are at risk of developing pressure ulcers (Waterlow, 1997) , there is still no agreement about the best scale to measure this risk in different populations of children. Before 1992, there was no risk scale designed to be used in paediatrics, as the first report about a scoring system of PUs for children was published in 1993 (Bedi, 1993). The Bedi tool, developed in one paediatric unit where the majority of cases were cardiac, it was a version of the adult Waterlow Card (1985) with modifications to its contents applicable to paediatrics.

Bedi's wound risk assessment chart was designed for children aged from birth up to 15 years old and consisted of 11 items: weight, continence, skin types, mobility, appetite, age, general assessment, special risks, neurological deficit, major

surgery/trauma, and medications. Also, this tool included a special part for describing the characteristics of wounds and swabs. Each item has a score range between zero and eight. Children are deemed at risk with total scores of 10+, at high risk with scores of 15+, and at very high risk with scores of 20+.

There are many RASs available for adults but only a limited number in paediatrics. No RAS based on quantitative data has been established in paediatrics (Willock et al., 2000) and most existing paediatric RASs are based on observation and clinical experience, and lack empirical evidence (Loman, 2000).

The Glamorgan RAS is the only scale that has been developed based on the statistical analysis of data collected by observing patients directly (Anthony et al., 2010, Willock et al., 2007). Many RASs used in paediatrics are modified versions of scales originally designed for adults. However, this has been found to be inadequate, especially if used in the PICU (Bedi, 1993, Cockett, 1998, Olding and Patterson, 1998a).

Modified adult RASs are argued to be inappropriate for children because of their different developmental and physiological characteristics. For example, immobility and incontinence are normal conditions in some paediatric groups such as neonates and differences such as these should be taken into consideration while estimating children's level of risk in regard to developing PU. Variations in age should also be accounted for while considering the use of a paediatric RAS (Willock et al., 2000).

One tool, which was developed in a hospital by Pickersgill (1997) as a part of a tissue viability policy, includes six items with total risk scores ranging from zero to 18, where zero is the lowest risk and 18 the highest. Items include: build and weight for height, appetite, skin condition, mobility, elimination and drugs used. These criteria were devised from Medley and Waterlow's risk score charts.

Another tool, which was developed in 1998, especially for children in PICU, contains 10 items with three to five sub-items for each (Cockett, 1998). The total risk score ranges from 2 to 36, where 2 represent the lowest risk score and 36 the highest. The items included are: weight, mobility, skin condition, diet, sedation,

hemodynamic status, respiratory status, incontinence, Glasgow Coma Scale score and other special considerations including having a temperature less than 35˚C, surgery longer than 4 hours, cast or splinted arm with intravenous fluids. These items were established based on a search of the literature for any known risk factors among paediatric and intensive care patients (Cockett, 1998).

For neonates, one study was found which aimed to design an instrument to measure the risk of acquiring PU in this population. The Neonatal Skin Risk Assessment Scale (NSRAS) (Huffines and Logsdon, 1997) was developed based on the adult Braden Risk Scale and consisted of 6 sub-items (general physical condition, mental state, mobility, activity, nutrition and moisture). Neonates' physical condition was scored according to their gestational age. A score of 1- was given to babies born at 38 weeks up to- post term, score 2 for 33-38 weeks, score 3 for 28-33 weeks, and a score of 4 for a gestational age of less than 28 weeks.

The other sub-items were scored according to a specific description of each item. Total scores ranged from 6 up to 24, with the lowest score indicating a lower risk and highest scores signalling highest risk. This scale was then modified following an inter-rater reliability test; the modified scale included only three sub-items (general physical condition, activity, and nutrition) which had shown the best inter-rater reliability (Huffines and Logsdon, 1997).

Another infant and neonatal RAS, the Neonatal / Infant Braden Q RAS, a modification of the adult Braden Q scale, was developed to measure prevalence in this particular population (McLane et al., 2004). The modifications were made by a neonatal clinical nurse specialist and a Wound and Ostomy Care paediatric nurse practitioner (WOCN) and included adding more descriptors for each sub-item to account for the unique characteristics of neonates, and adding a new gestational age category to target premature infants (McLane et al., 2004).

Garvin (1997) established an assessment and intervention tool for pressure-related skin breakdown in paediatric patients. The tool consists of four categories (mobility, sensory perception, nutrition and moisture), each of which has a classification of four

stages ranging from 1 (low risk) to 4 (highest risk). The total score ranges from 4 (no risk) up to 16 (the highest risk). It is also includes intervention categories ranging from level one to three. These interventions would be applied for each child according to their risk score, based on the same tool.

Another scale which has been developed and used to assess children is the Pattold risk scale. This scoring system was first developed by Olding and Patterson (1998) to measure the risk of PU development in children in ICUs. The PICU unit was chosen specifically because of the high frequency of skin damage noticed in this particular unit (Jones et al., 2001, Willock and Maylor, 2004).

One section of the Pattold scale includes eight areas that were found to be significant for skin integrity maintenance, and which were specified based on the authors' experience as PICU nurses, and the results of two questionnaires posted out to several PICUs within the UK. The areas are: cardiovascular, temperature, respiratory, mobility, nutrition, continence, skin condition, and weight status. For each, a score from 1 to 3 would be given after an examination of the child's skin is completed. This part of the scale is followed by sections detailing the type of action and the equipment used.

This scale was then further modified by the addition of a skin assessment policy and other factors related to PU management. The rest of the scale comprises a daily evaluation of seven major areas of a child's skin that are especially prone to skin damage. These are the occiput, ears, nose, shoulders, sacrum, hips and heels. PU characteristics would be documented in a specific part of the tool, and a classification system with six different categories is provided. Ulcers range from category *I*: redness (Blanchable-Erythema), to category *VI*: body cavities (including two or more PUs that merge together into one cavity sore). The total score is then calculated to classify patients into three possible categories of risk: low, medium, and high (Jones et al., 2001).

Another attempt to develop a paediatric pressure ulcer risk assessment tool was made by Barnes (2004). This tool consists of two pages. The first is composed of a list of

questions related to risk factors identified from previous literature, as recommended by Waterlow (1998). The same page also has space for nurses to record any preventive actions they have taken, and a table of suggested interventions. The second page has space for the documentation of any details of skin assessment or any change in skin integrity. Also, a body map is provided so that the location of the skin problem can be clearly stated. Any child who is found to be at risk according to this scale, would have a full assessment form filled in (Barnes, 2004).

Several amendments were later applied to this tool, including the addition of further questions in the assessment section and the insertion of two more documents: the skin assessment care plan and the wound care plan. Types of skin problems to be focused on during assessment include persisting Erythema, non-Blanchable hyperaemia, blisters, and discoloration, as well as oedema and localised heat or purple discoloration, on the dark skin children (Barnes, 2004).

Another tool which was a modification of the Braden Q scale is the Starkid Skin Scale (Suddaby et al., 2005) which was intended as a simple single-paged measurement tool for skin breakdown in children. The scale was created by two clinical nurse specialists who reworded and simplified the concepts that were originally stated in the Braden Q scale. The newly developed tool consists of six sub-items, as in the Braden Q, but activity and mobility have been combined as one category, since the two concepts are thought to be closely related. One more modification was the addition of a bold font for the key elements of each sub-score, which is intended to draw nurses' attention to the significant part of the scoring for each item (Suddaby et al., 2005).

The last tool that was identified in the literature was the Braden Q+P scale (Galvin and Curley, 2012), which is another modification of the Braden Q Scale. It was developed as an assessment and prevention tool for pressure-related skin injuries, as part of one hospital's comprehensive PU prevention plan. It is applied to cardiac surgery patients and main surgery patients, such as those undergoing orthopaedic surgery, and it includes preoperative PU risk assessments, pre-procedure and post-procedure skin assessments, positioning, and clinical interventions.

The tool is a one-page assessment of patient risk and a plan of preventive interventions for PU, in which six out of seven of the Braden Q scale sub-items were modified and included. The 'activity' sub-item was removed because all OR patients are sedated. 'Mobility' was included under the 'intensity and duration' element, to determine the effect of lengthy procedures on PU formation. Moreover, the scoring is based on yes / no answers for each item, while each item on the scale has a suggested list of preventive interventions designed to help stave off PU development in surgical patients (Galvin and Curley, 2012).

2.5.2.1 The Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale

This scale was developed based on data collected on 336 paediatric inpatients from 11 hospitals in the United Kingdom (UK) in 2007. Sixty one children were observed to be affected with PU in a prevalence and incidence survey (Willock et al., 2007). The characteristics of those children who had PU and those who did not were then compared. By using the *Chi Square(X^2)* statistical test, any characteristic found not to be statistically significant ($P > 0.01$) was excluded from the scale, and eleven out of the 17 variables identified were included in the scale as sub-items.

Some items were merged together, like *immobility* and *difficult to position*, as it was thought by the authors that both of these terms measured the same variable, and further amendments were made after a reliability study of the scale was undertaken (Willock et al., 2008), which included further changes to the *nutrition* sub-item. The final scale included 9 sub-items. The risk scores were adjusted so that patients with higher scores would be those at higher risk of developing PU. The total scores were classified as follows:

Total score of ≥ 10: at risk.

Total score of ≥ 15: high risk.

Total score of ≥ 20: very high risk.

a) Content validity of the Glamorgan Scale:

The content validity of the scale was ensured by its developers by the omission of any item which was not found to be statistically significant. In addition, adjustments were made to some sub-item scores which made them more valid in terms of being able to predict the risk of PU occurrence in this population. These adjustments in scoring aimed to reflect the significance of the association between each sub-item and PU development. *Immobility*, for example, was given a higher score (20) compared with the rest of the sub-items in the scale. This was justified by the strong association that was found between this item and PU development. This is unlike most PU risk scales, however, which tend to give the different sub-items the same range of scores (Willock et al., 2009).

The main terms used in the Glamorgan RAS, with its related definitions and risk scores are presented in (Appendix 1.8), based on special guidance on using the Glamorgan, which was provided by the scale's developer (Appendix 3.3).

b) Sensitivity and Specificity / Predictive Validity of the Glamorgan Scale:

Sensitivity and specificity are crucial tests for a risk tool. A risk scale's ability to detect the occurrence or non-occurrence of a particular condition in a specific group is highly dependent on these two concepts. Sensitivity is a measure which tests a scale's ability to detect the truly affected subjects of a certain condition in a larger group of people. Specificity, on the other hand, is a measure which tests a scale's ability to identify subjects who truly would not go on to develop a specific condition (Anthony, 1996).

The sensitivity and specificity of the Glamorgan scale was tested on the same population that had also been used to develop the scale. Based on a risk score of 10, the Glamorgan was 100% sensitive (the scale was able to classify all children who did in fact develop PU as at risk), but only 50.2% specific, meaning that the scale was able to correctly classify only 50.2% of the children who did not develop ulcers as not at risk (Willock et al., 2009). In other words, all the children who did develop

PU scored 10 or more according to the Glamorgan scale, whereas only around 50% of the children who did not develop PU scored less than 10.

As already noted, not only with the Glamorgan, but also in all other PU risk scales, any effort to increase the sensitivity of the scale would result in a reduction of its specificity (a higher number of false positives). Hence, the ability of scales to truly detect subjects at risk of particular condition is usually tested by measuring their predictive validity, rather than their specificity and sensitivity values alone. Predictive validity is 'the degree to which an instrument is able to predict an observed criterion over future period of time' (Polit and Beck, 2010, p.378). This is usually measured by the Receiver Operating Characteristic Analysis (ROC), defined as a technique to assess the classification ability of a certain test or scale (Anthony, 1996).

The predictive validity of the Glamorgan scale was tested through the ROC curve based on the same sample as previously mentioned. The ROC curve is a plot of the true positives (sensitivity) against the false positives (1- specificity) on a range of different thresholds (Anthony, 1996). The area under the curve (AUC) is calculated and used to help clarify that any randomly selected subject at risk of PU would have a higher risk score than any randomly selected free-of-risk subject. The AUC for the Glamorgan scale was found to be 0.912 (high predictive validity) (Anthony et al., 2010). This score means that 91% of the time, a randomly selected child judged to be at risk of PU would have a higher risk score than any randomly selected free-of-risk child from the same sample (Willock et al., 2009).

Another recent abstract paper compared the predictive validity of the Glamorgan with that of the Braden Q RAS. This revealed that the AUC for both scales were the same, although the Glamorgan was slightly more sensitive that the Braden Q (Long et al., 2011). However, no more details about these AUC values were provided.

An area under the curve equal to 1.0 for a risk scale means that this scale will be 100% accurate every time a risk subject is selected. If the area under the curve is equal to 0.5, this would mean that there is no predictive value for this scale. When

the value under the curve is closer to 1.0, that means the scale has a higher predictive ability (Anthony, 1996).

In summary, this scale was found to be predictive of PU formation in general paediatric population, taking into consideration the different weightings of the *mobility* and the *equipment pressing on skin* sub-items on the scale, this could also reflect the significance of these particular sub-items, which would in its turn increases the duration of time of any existing pressure, while at the same time produces different friction and shear forces on patients' skin, especially over bony prominences while positioned or sliding down in their beds.

c) Inter-rater Reliability of the Glamorgan RAS:

Inter-rater reliability is the consistency with which two or more researchers observe and record the same behaviour in the same way on different occasions (Parahoo, 2006). The level of agreement or disagreement between researchers observing a particular phenomenon is usually measured by calculating a correlation coefficient. This coefficient can be found by asking two or more observers to record the same event separately then comparing their findings. A correlation coefficient closer to 1.0 means more reliable findings and that the observers have a high degree of agreement with each other in how they observed and recorded an event on separate occasions. However, a correlation coefficient of less than 0.6 indicates a very low level of agreement between the observers' ratings and hence lower reliability (Parahoo, 2006).

The Glamorgan Risk Assessment Scale has been shown to be reliable in one study (Willock et al., 2008) which compared the ratings of 15 randomly selected paediatric nurses with the researcher's own rating. Both the nurses and the researcher scored 15 children in one hospital independently. After that, their risk ratings were compared using SPSS and it was found that there was 100% agreement between the risk ratings of the researcher and the nurses in eight out of nine of the Glamorgan sub-items. *Inadequate nutrition* was the only sub-item with 93% agreement with Cohen's

Kappa 0.63 (*P< 0.01*). All other sub-items Cohen's Kappa were 1.00 (*P< 0.001*). These values of the correlation coefficients suggested strong reliability for the scale, with even the nutrition sub-score showing good agreement.

Later, the authors changed the *inadequate nutrition* sub-item description to *inadequate nutrition - consult a dietician if in doubt*, to reflect previous knowledge of the child's age, medical condition, previous body mass index and others. These modifications were thought to be of benefit in enhancing the reliability and validity of the scale. Willock et al. (2008) believe that any tool that is not reliable is not valid, because it would not actually measure the phenomena it is supposed to measure.

In contrast to this, an observational study carried out in one hospital's cardiac unit investigated the inter-rater reliability and agreement issue of the Glamorgan sub-items and total scores. The nurses' inter-rater agreement on the existence or absence of an item for each child was relatively high. The highest was the *significant anaemia* sub-item score (P_0= 100%), while the lowest agreement was for the *mobility* sub-item (P_0= 82%). However, the inter-rater reliability of the Glamorgan total risk score, between the 27 nurses who randomly scored 30 children for PU risk in groups of three nurses at a time, was low (Cohen's Kappa 0.34 (95% CI 0.12-0.57)). The agreement on the Glamorgan total score was 48% (Kottner et al., 2012).

According to Kottner et al. (2012), these figures indicate that the Glamorgan sub-items were clearly described, so many nurses agreed on the existence or absence of each feature for most children (inter-rater agreement) but, with low inter-rater reliability coefficients', indicating that nurses were unable to identify children at risk of PU based on their sub-items and total score. More than half of the nurses produced different scores for children's total risk. However, this might be due to the generally low risk of PU in this unit, which made it difficult to identify children at risk efficiently (Kottner et al., 2012).

According to the studies discussed above, the Glamorgan Scale has low inter-rater reliability when used in critical care units, such as the cardiac unit. This might be

related to its better performance in the paediatric general wards and specialities, within which it was initially developed to be applied.

2.5.2.2 The Braden Q Pressure Ulcer Risk Assessment Scale

The early development of this tool was based on modifications to the adult Braden RAS (Braden and Bergstrom, 1989). It was created to be used in paediatrics, and is thought to be beneficial because of its diverse range of vital sub-items, which the original authors believed to be the major causes of PU development (Quigley and Curley, 1996). These items were actually derived from Braden and Bergstrom's conceptual model, which divided risk factors into two groups related to skin tolerance and to the intensity and duration of the pressure (Bergstrom et al., 1987). In addition, the adult Braden Scale is widely applied and tested in various hospital wards including the ICUs (Quigley and Curley, 1996).

The Braden Q Scale is composed of seven sub-items; *mobility*, *activity*, *moisture*, *tissue perfusion & oxygenation*, *friction and shear*, *sensory perception* and *nutrition*. Each sub-item is scored from 1 to 4, with 4 representing the lowest level of risk and one indicating the highest risk. The total score for any child should range from seven (the highest risk) to 28 (no risk) (Quigley and Curley, 1996).

These sub-items are the same as those found in the adult Braden scale, but with the addition of the seventh sub-item, *tissue perfusion and oxygenation*. This item was added to reflect the unique paediatric developmental characteristics, and to optimize the benefits of using data that are commonly available in paediatric intensive care units. On the other hand, this sub-item also related to the original conceptual model which was used to develop the adult Braden Scale (Quigley and Curley, 1996).

According to Braden and Bergstrom's conceptual model (Braden and Bergstrom, 1987), the sub-items of the Braden Q Scale could be divided into two groups, one related to the intensity and duration of pressure (*mobility, activity and sensory perception*), and the other related to tissue tolerance to pressure, and divided further into 'intrinsic factors'; *nutrition and tissue oxygenation and perfusion*, and 'extrinsic factors'; *friction and shear* and *skin moisture*.

The modifications that were made to the adult Braden Scale in order to create the Braden Q RAS include (Curley et al., 2003b):

- Changing the definition of some sub-items, or adding a different description such as in the case of the 'very limited' *mobility* sub-item. Also, considering all patients who are unable to walk due to developmental perspectives as 'walks frequently' in the activity sub-score, and clarifying the definition of sensory perception in a way which took the developmental stage of the child into consideration.

- Adding drainage as an option to be considered while scoring moisture, and adding 'routine diaper change' to the 'rarely moist' sub-item. Also, linen changing, a part of the *moisture* sub-item, was described in a more precise manner, by considering hours rather than shifts.

- Applying operational definitions to differentiate between *friction* and *shear* forces. Also, splitting the Braden scale's first level into two levels: '1- Significant problem' and '2 - Problem' so that the scores would range from one to four, along with the rest of the scale's sub-items.

- In terms of nutrition, 'bottle or breast feeds' were added as descriptors for meals. 'Albumin less than 2.5 mg/dl' was added to the first level of the scale, 'very poor', and 'less than 3 mg/dl' was added to the second level, 'inadequate'. Moreover, a new statement was added to the other three levels to describe whether the child was on a normal diet or on enteral or parenteral feeding, and whether this type of feeding adequately met the child's calorie expenditure.

- Adding *Tissue perfusion and Oxygenation* as a seventh sub-item for the scale. This sub-item has four levels to describe the child's circulation and tissue perfusion level and includes data related to blood pressure, capillary refill time, PH level, O2 saturation and Haemoglobin level.

The amendments discussed above were thought by the authors to be beneficial, in that they would reflect the unique paediatric developmental characteristics, and optimize the benefits of using data that are commonly available in paediatric intensive care units, such as information obtained by blood sampling, and non-invasive technology. In addition, it was thought that one sub-item, *nutrition*, would be helpful in estimating the prevalence of using enteral and parenteral feedings in these units (Curley et al., 2003b).

The addition, the *Tissue perfusion and Oxygenation* sub-item was considered a crucial indicator of PU risk, especially in ICUs. Patients with compromised circulation would exhibit some sort of blood shifting from their non-vital organs, including their skin, to vital organs, such as the heart or kidneys, as a way of compensating for their diminished tissue perfusion. This decrease in skin perfusion would increase patients' risk for local compression and ischemia (Curley et al., 2003b).

Also, patients' hemodynamic instability was shown to be one of the major factors that lead nurses to position patients in ICUs infrequently (Neidig et al., 1989). Moreover, this sub-item was found to be related to the original conceptual model which was used to develop the Adult Braden Scale (Quigley and Curley, 1996).

a) Content Validity of the Braden Q RAS:

The content validity of the Braden Q RAS was established by a group of paediatric nurses with a special interest in skin issues. A total of 178 paediatric inpatients were scored by this group of expert nurses, using the scale. At the same time, each child was classified by a bed-side nurse into one of three risk categories, low, moderate or high, based on the personal judgement of these nurses.

By combining the Braden Q scores with the bed-side nurses' judgement, children found at low risk for skin breakdown scored an average of 25 points. Children with moderate risk scored, on average, 21 points and children with high risk were found to score an average of 16 points. With confidence intervals indicating that children who scored less than 23 points were at moderate to high risk, any child scoring less

than this cut-off point was classified as being at risk of skin breakdown according to the Braden Q Scale (Quigley and Curley, 1996).

Furthermore, any child who scored 16 points or less on the Braden Q Scale was classified as at high risk of developing PU and could be considered at risk of acquiring category *II and above* PUs (Curley et al., 2003b). However, a cut-off score of 16 was used to test the predictive validity of the Braden Q scale for this thesis. This score was recommended by the authors of the scale to distinguish between children 'at risk' and 'not at risk', and it is also believed to be useful in terms of allowing nurses to make decisions about when to apply intervention measures aimed at preventing PU, where any child scoring ≤ 16 should been prescribed prevention aids. The authors believed that classifying risk as high, medium, or low is irrelevant (Noonan et al., 2011).

The main terms and categories of the Braden Q RAS with their related definitions, based on Noonan et al. (2011) are presented in (Appendix 1.9).

b) Sensitivity and Specificity / Predictive Validity of the Braden Q RAS:

To determine the predictive validity of the Braden Q RAS, Curley et al. (2003a) implemented a prospective cohort descriptive study in three PICUs, with a total sample of 322 patients. The patients' ages ranged between 21 days and eight years old. Four major age categories were created and a maximum of 30 patients were selected for each category from each PICU, to ensure the equality of sample age across the study. These age groups were classified as a) infants (21 days to 12 months); b) toddler (12 to 36 months); c) preschool (3 to 5 years); and d) young school (5 to 8 years).

Besides the principal investigator, the children were scored by a group of trained site investigators and research assistants, at first as a team to ensure clarity of the scale's sub-items, and then ten children each were scored independently by the team members until there was 90% agreement on the Braden Q scores. Two other nurses blindly to others scored and assessed each child on admission, and three times each

week for the first two weeks, then weekly until the child discharged from the PICU. This study resulted in an incidence rate of 27% for category *II* and above PUs (Curley et al., 2003a).

Using data from the previous study (Curley et al., 2003a), excluding category *I* PUs, the AUC was 0.83. With a cut-off score of 16, the sensitivity for the Braden Q was 0.88 and the specificity was 0.58. The ROC curve was then constructed for each sub-item of the Braden Q RAS. Only 3 sub-items had an AUC greater than 0.7. These sub-scales were *mobility*, *sensory perception* and *tissue perfusion and oxygenation.* The Braden Q scale then was modified to include only these three sub-scales, which contributed to an AUC > 0.7. The shorter version of the Braden Q Scale showed an AUC of 0.84. With a cut-off score of 7, the sensitivity and specificity were 0.92, and 0.59 respectively (Curley et al., 2003b).

Even though the modified Braden Q Scale performed as well as the whole Braden Q scale, the authors still recommended using the scale as a whole, especially since other sub-items might be significant in other paediatric wards than ICUs. The researchers recommended further work on this point (Curley et al., 2003b).

One study was set up to compare the predictive validity of the Glamorgan, Braden Q and Garvin RASs (Anthony et al., 2010). Use of univariate statistical tests (Chi square and Mann Whitney) showed that seven out of ten of the Glamorgan sub-items were significant, compared with four out of seven in the Braden Q and two out of four in the Garvin Scale.

The three scales were also tested through *LR* analysis, which showed five sub-items of the Glamorgan, three of the Braden Q and two sub-items of the Garvin scale to be significant (Anthony et al., 2010). The AUC of the Glamorgan total score was better than that of the Braden Q or Garvin (0.912 vs. 0.694 and 0.641 respectively).

These findings indicated that the Glamorgan was superior to the other two scales in terms predicting the risk of PU in the general paediatric population. However, this finding may need further investigation since the study used a retrospective design (Anthony et al., 2010). Furthermore, these values were calculated based on the same

data that was initially used to develop the Glamorgan scale. This may have unfairly influenced the findings in a manner which meant that the Glamorgan emerged to be the best of the three scales.

c) Inter-Rater Reliability of the Braden Q RAS:

Two studies have discussed the issue of the Braden Q scale's inter-rater reliability (Curley et al., 2003b, Noonan et al., 2006) although neither was established specifically to measure this feature. One point prevalence survey (Noonan et al., 2006) was conducted among 252 paediatric inpatients at one hospital, where the Braden Q Scale was one of 12 data elements used in an audit tool to measure the prevalence of skin breakdown.

Two hours of training was offered to the participating auditors, which was followed by a 16- item test to assess inter-rater agreement on the Braden Q Scale sub-items, and on assessing two other types of skin breakdown, as well as PU. The participants were able independently to reach 100% agreement within one point of the Braden Q Scale. For the same study, two expert nurses in PU also categorised all the identified ulcers, these nurses had reached 90% agreement in categorising 50 PU' photographs prior to the audit (Noonan et al., 2006).

Another prospective cohort study was conducted on 322 inpatients to establish the predictive validity of the Braden Q Scale (Curley et al., 2003b). Prior to data collection, the primary investigator trained all site investigators and research assistants (students and PICU nurses) on how to score the Braden Q and how to categorise PUs.

The whole team scored PU as a group until clarity of the concepts included in the scale's sub-items was guaranteed. Ten patients were scored by each auditor independently until 90% agreement of Braden Q scores was reached. Also, it was required that the scoring of each sub-item of the scale would not vary from one participant to another in more than one point.

As shown above, a number of studies have used their own varied methods to measure inter-rater reliability for this scale. Training was usually provided to auditors before each study was conducted but this means that there is a lack of evidence available to show whether there would be agreement on the scoring without such training being given. This is important because the point of using a specific scale is for it to be clear enough for any bedside nurse to fill in when necessary, without having been specially trained.

A further trial to measure the inter-rater reliability of another assessment tool for PU and other skin breakdown in children and neonates, the Starkid skin scale, which was a modification of the Braden Q scale, was conducted by (Suddaby et al., 2005). The scale was shown to have inter-rater reliability of 0.85, with the nutrition sub-item being the least reliable. The sensitivity of the scale was low (17.5%) but it was found to have high specificity (98.5%) (Suddaby et al., 2005).

Finally, having a glance at this section, it would be noticeable that most paediatric PU RASs originated from PU risk scales designed for adults, and that many others are modifications of the paediatric Braden Q scale. Three out of the thirteen scales identified were established based on the Waterlow risk scale (Pickersgill, 1997, Bedi, 1993, Waterlow, 1998) and two more were adult Braden scale modifications (Huffines and Logsdon, 1997, Quigley and Curley, 1996).

Additionally, three of the scales were modifications of the paediatric Braden Q RAS, where either certain categories had been omitted or new indicators had been added to an existing category, to make the scale suitable for a particular population of children (Suddaby et al., 2005, McLane et al., 2004, Galvin and Curley, 2012). In brief, more than half of the scales found in the literature were modifications of other pre-existing tools. A summary of all identified Paediatric RASs is provided in (Appendix 1.6).

2.6 THEORETICAL FRAMEWORK OF THE STUDY

Risk assessment has become a major task for nurses and all health care professionals. It is very challenging to provide a high standard quality of care, and to detect any health risks the patients may encounter during their hospital admission and the complex environments of modern hospital wards, especially ICUs, make it more difficult for nurses to recognise signals of patients risk properly (Despins et al., 2010).

Children and neonates admitted to ICUs have often been described in previous literature to be at higher risk of adverse effects, including PU, more than the paediatric patients in general wards (Zollo et al., 1996, Willock and Maylor, 2004, Curley et al., 2000). Critical units were noticed to predispose children to a higher risk of PU development, because of their high technology, use of invasive and complicated medical equipment, and the acute physiological conditions of these children compared with children in general wards (Garvin, 1997, Schindler et al., 2007).

All of these studies shown it is crucial to have a strategy to predict the possibility of these high risk patients encountering harm, or being affected by factors which contribute to PU. Since most of the time the nurse is the primary bedside carer for the patient, and hence, he or she would spend the largest amount of time with them, any risk, or hazard should be discovered first by the nurse (Despins et al., 2010).

Moreover, ICU nurses are required to identify risk in a complex surrounding environment, which means they may be more chance of them missing a risk factor. Nurses would encounter various inter-related factors amongst which some would actually be associated with PU formation, while others would not. The acute condition of ICU patients, the multiple use of complex devices, and the continuous application of prevention and intervention measures, in addition to many other duties, such as paper work and ward-related works, could all collectively have a negative effect on the nurses' abilities and their focus on risk and hazards. Within this very loud and busy environment, the nurse still needs to detect any signal of patients' risk as early as possible.

The situation described in the previous paragraph closely reflects the assumptions of the theoretical framework which was used in this study: the Signal Detection Theory (SDT) (Green and Swets, 1966). It was selected to guide the current work because of the relevance of its major concepts and propositions. According to this theory, any person in an uncertain situation who needs to make a decision, would encounter some obstacles in detecting signals from the surrounding noise (Abdi, 2007). However, these obstacles would depend on both the observer's response, and the amount of 'noise', as well as the signal's strength (Heeger, 2003).

2.6.1 Major Concepts and Propositions of SDT

SDT has been previously used as a framework to study decision making by people in uncertain or vague situations, and has helped to show how an observer's subjective opinion, thoughts, and knowledge might affect his ability to identify an existing physical stimulus (Wickens, 2001).

This theory has three major concepts as follows:

- ***The Stimuli*** are the variables that exist in a certain experiment or situation. The stimuli would be either noise only (no existence of the condition), or a signal with noise (with the existence of the condition). A signal is the target stimulus that needs to be detected correctly within a group of surrounding stimuli or interfering information, called the noise (Wickens, 2001, Despins et al., 2010, Abdi, 2007).

- ***The Observer*** is the person in a certain experiment or situation who has a decision to makes. This person needs to correctly classify the stimuli either as being relevant (signal), or irrelevant (surrounding noise only). This decision making process depends on several factors, such as the observer's sensitivity in detecting signals, where sensitivity is the ability of the observer to correctly distinguish a true signal from other surrounding noisy stimuli. Sensitivity, in

turn, depends on other factors, such as the observer's level of training and experience, the amount of information available, and some physiological issues such as fatigue. Also, the decision would depend on the strength of the stimuli compared with the background noise, as well as on the amount of surrounding noise (Despins et al., 2010, Wickens, 2001).

The observer's level of experience and knowledge will certainly affect his or her ability to choose one response over the other. As knowledge about a specific condition increases, the observer's ability to distinguish true signals will be much improved. On the other hand, if the signal (the target condition) is strong, the observer can easily detect it over weaker noise, and the chance of error will be reduced. Furthermore, when environmental noise is scant, it would be easier for the observer to detect a signal than if that signal was hidden by a large amount of loud noise (Heeger, 2003, Wickens, 2001).

- ***The Response*** is the observer's 'yes' or 'no' detection of a signal. When a signal exists, the response would be either correctly detected (called 'hits'), or incorrectly not detected ('miss'). In contrast, if the signal is absent, the response would be either correctly not detected ('correctly rejected'), or incorrectly detected ('false alarms'). These four conditions of response are shown in table 2.2.

Table 2.2: Possible Responses of SDT

Signal type	**Response**		
		Yes	**No**
	True Signal	Hit	Miss
	Noise	False alarm	Correct rejection

In SDT, hits and false alarms complement each other. Hypothetically, if *hits* comprise 50% (0.5) of the 'Yes' responses, the *false alarms* would account for the other 50% (0.5), and the total for both will equal one. However, in reality, *hits* and *false alarms* would complement each other according to the actual situation; for example, if 30% of the observer's 'Yes' responses were *hits*, then *false alarms* would account for the

remaining 70%. Therefore, to identify how well the observer has performed in detecting signals and noise, both values should be calculated, as the number of hits the observer had achieved in one trial is not a good enough indicator of his or her ability to detect signals correctly (Wickens, 2001).

Not surprisingly, the number of *misses* and of *correct rejections* would also complement each other, with total 'No' responses accounts for one (100%). Misses and correct rejections are calculated based on the *hits* ratio (*h*), and *false alarms* ratio (*f*).

$$h = \frac{\text{No. of Hits}}{\text{No. of Signal conditions}} \qquad f = \frac{\text{No. of False alarms}}{\text{No. of Noise only conditions}}$$

- Misses Rate = 1- *h*.

- Correct rejection Rate = 1- *f*.

The concepts *hits* and *false alarms* are used interchangeably with other concepts in different disciplines. In epidemiology, *hits* are called the *true positives*, and *false alarms* are the *false positives*. Moreover, the *h ratio* is the same as 'sensitivity', and the *correct rejection ratio* (1- *f*) is 'specificity'.

If a person can easily distinguish true signals from surrounding noise, he or she can more often than not make a correct decision regarding the chance of a specific condition occurring. In many situations, it is easy for an observer to distinguish the true signals of some condition from other surrounding fake stimuli (noise), but the difficultly is making a decision to take action based on any of these signals, and knowing whether this decision is correct or not (Wickens, 2001).

2.6.2 PROBABILITY OF OCCURRENCE CURVES

SDT is illustrated in (figure 2.2). A noise-only situation and a signal-noise situation are represented by two curves, which show their likelihood of occurrence. In a noise situation, there is only irrelevant noise and no existence of the target condition. In a

signal-noise situation, on the other hand, the target condition exists inside of a noisy environment but the researcher cannot completely isolate the true signal without having a chance of encountering noise stimuli (Heeger, 2003).

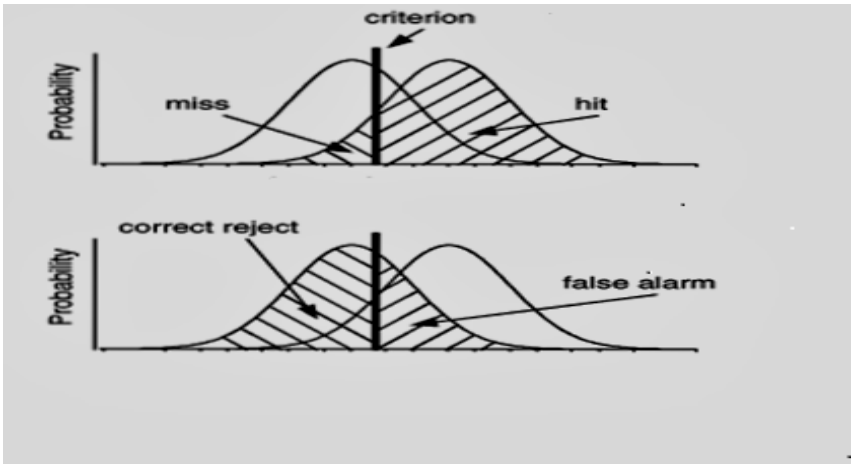

Figure 2.2: SDT Probability Curves

The theory raises the idea that there is a criterion upon which the observers base their responses to stimuli. This criterion is pre-specified, usually depends on the observer's previous experience, training, and knowledge and it helps the observers see the trend of their responses. If the stimulus is higher or greater than the criterion value, then the response to a signal's existence (the condition) would be mostly 'Yes'. If the stimulus was less than the criterion, then most observers' responses would tend to be 'No' (Thompson et al., 2008, Heeger, 2003).

Setting the criterion at a low level will increase the number of hits, because most observer responses would tend to be 'Yes'. However, this would also increase the number of false alarms. On the other hand, when the criterion is set at a high level, the observers' responses would tend to be 'No' and this would increase the chance of missing true signals, and increasing the number of correct rejections. Nonetheless, there is always an area of overlap between the responses to noise situations, and noise-signal situations. This means that whatever the stated criterion, there is always an unpreventable chance of error by observers (Heeger, 2003).

Many of the SDT's concepts and propositions are key elements in the current study. Since nurses, especially those who work in critical care units, need to correctly identify the contributing risk factors of PU development among their patients, they are here the observers, and detecting the true risk factors of PU is like detecting the true signals from noise. For example, a child in PICU who has a low albumin level might be categorised as at risk by nurses who believe that low albumin level is a risk factor for PU formation. However, this factor has not yet been proven to be a true contributing factor of PU occurrence in critically ill children.

The use of an RAS also could be said to be guided by the same theory, since nurses would use the scale to make decisions about patients' risk of PU occurrence based on a specific criterion, the scale's cut-off score. For example, a child who scores less than 16 on the Braden Q RAS would be classified by the nurse as at risk, yet it would be as yet unknown whether the child would actually develop an ulcer later or not.

All of the findings of this research are discussed thoroughly, in light of this theory's main concepts and assumptions, later on in the discussion chapter.

2.7 **SUMMARY**

This chapter aimed to review previous literature regarding the problem of PU among children and neonates. Prior research was crucial in enhancing the research process of this study, in a way that sheds light on their main findings. Focusing on the strengths and further investigating the weaknesses of previous research changed the way in which the current study was carried out and improved its performance.

In this thesis, a number of specific search strategies were applied, including the use a pre-specified list of key search terms to ensure that the literature search was focused within the main inquiry of the current study. The major themes in this research were the PU problem size in paediatrics, calculated through incidence and prevalence rates, and PU risk in children, with a focus on both risk factors, and commonly used risk scales.

Moreover, a theoretical framework was chosen as a basis for the current work. Through using the SDT, the research questions and hypotheses were formulated. Moreover, the findings of the study could be discussed based on the main concepts and propositions of the theory. Also, all the incidence and prevalence studies investigated, and the established paediatric RASs examined, were summarised in specific tables in order to facilitate their applicability and usage, and to clarify the main findings and properties of each in a brief organised manner.

Finally, prevalence and incidence rates of PUs in paediatrics vary widely. This might be explained by the fact that different studies have used different methods of data collection, have taken place in different settings (multi-centre, or single sites), have involved different populations (for example, burn, critically ill, or general ward patients), and have used different data collection methods. Different studies may also rely on different definitions of PU and other skin breakdown problems, or use different classification systems. For example, which categories of ulcers are included or excluded, and which skin problems are considered to be PUs, are thought to be significant in causing variation across paediatric studies.

CHAPTER THREE:

METHODOLOGY

3.1 A GLANCE AT THE CHAPTER

This chapter comprises a description of the methods used in this research. It contains information about the study design, the data collection tools and procedures, the research questions, and an explanation of the data analysis processes.

An explanation of how the sample for the study was chosen, rationales and any justifications are also offered. In addition, this chapter includes details about the validity of both the Glamorgan and the Braden Q risk scales, which were used to collect data from the study sample.

In more detail, this chapter focuses on the research design of both the prevalence and incidence studies. A thorough description of each study and a comparison between the two is provided. The unique research design, procedures, sample, population, and data analysis for each study are all mentioned.

Finally, a brief account of the theoretical framework is provided in order to help explain how the main research questions were formulated and why the data collection and analysis processes were applied.

3.2 THE RESEARCH APPROACH

Research is a basic element of all disciplines, which is adopted to help generate knowledge, or to improve existing knowledge. It consists of a systematic process that uses organised methods to answer a question or to understand a problem (Polit and Beck, 2006).

Nursing is one discipline which requires continuous research in, for example, its clinical, administrative, and educational branches. This work helps to clarify different aspects of nursing care, and to answer evolving questions which might be encountered by nurses on a daily basis.

There are two broad approaches to conducting research, the quantitative and qualitative methods, in addition to the use of a mix of both, the mixed method. The Quantitative approach is usually used to answer research questions related to problem size, like in incidence and prevalence studies, or when the researcher is interested in identifying measurable attributes of a phenomenon (Polit and Beck, 2006). The Qualitative method, on the other hand, uses more in- depth methods such as interviews, to gain a deeper insight into the phenomenon' dimensions and variations.

However, nursing is a distinctive field with complex issues, especially considering that the main subjects in nursing research are human individuals, who have a highly complicated nature (Polit and Beck, 2006). As a result, a nursing researcher may need to use more than one approach in order to obtain a full picture of the phenomenon under investigation; this is called the Mixed Method approach.

In this thesis, however, the Quantitative approach is used due to the nature of the main inquiry, the related research questions and the major hypotheses. The quantitative approach is useful because it:

1- Allows the process of pressure ulcer (PU) development within the paediatric population to be identified and described. Help in allocating children who are at risk of PU development, to describe their characteristics and the identified risk factors.

2- Is helpful in calculating the incidence and prevalence rates, to estimate the size of this problem in the paediatric population.

3- Allows us to differentiate between the unique characteristics of PU children in critical care units and those who remained PU-free, while exploring the PU problem among critically ill children and neonates.

4- Helps to predict the risk of PU development in certain paediatric groups (the critically ill children and neonates), based on the use of two risk assessment scales (RASs), the Glamorgan and the Braden Q risk scale.

5- Classifies children, according to their risk scores, into groups (high risk, at risk, or not at risk) based on the Glamorgan, and (at risk, not at risk) according to the Braden Q RAS. It also classifies PUs into categories: *I, II, III, IV* according to the European Pressure Ulcer Advisory Panel (EPUAP) guidelines (EPUAP and NPUAP, 2009).

6- The results may enhance nurses' use of Evidence-Based practice by generating new statistically tested data.

3.3 THE RESEARCH DESIGN

3.3.1 Objectives:

This study aims to:

- Determine the size of the PU problem within the paediatric population in one university hospital (KAUH) in Jordan by conducting point prevalence, and prospective incidence studies.

- Underline the contributing factors (risk factors/ predictors) that predispose Jordanian children in critical care units to PU development.

- Establish and compare the predictive validity of two paediatric risk assessment scales, the Glamorgan RAS and the Braden Q Scale, among critically ill children.

3.3.2 Research Questions and Hypotheses

A research hypothesis is a prediction that is formulated by the researcher to answer the research question and which can be tested empirically. Research questions help the researcher to address the research problem as well as to guide the type of data to be collected (Polit and Beck, 2006).

Research questions can be used to replace the purpose statement, as this may help in focusing work and thoughts about the main problem and about the actual type of data that needs to be collected. In quantitative research, these questions identify the independent and dependent variables, the relationship between them and the population under investigation (Polit and Beck, 2006).

To help direct the research and identify the correct type of data to be collected, this study includes the following research questions:

1- What is the prevalence rate of PU among Jordanian paediatric inpatients?

2- What is the incidence rate of PU among Jordanian critically ill paediatric inpatients?

3- What are the factors that contribute to PU development among the Jordanian critically ill paediatrics?

4- Which scale, the Glamorgan RAS or the Braden Q RAS is more valid in predicting PU risk among the Jordanian critically ill paediatric inpatients?

As explained above, the questions were formulated before the collection of data commenced. For the incidence study, the independent variables (factors that contribute to PU development) and the dependent variable (PU development) were identified, while the population was specified as Jordanian critically ill paediatric inpatients. In addition, the relationship between the use of the Glamorgan and Braden Q RASs and the ability to actually predict the risk within the population under investigation was addressed.

Another aim of the study was to investigate the relationship between the risk factors and the development of PU, despite this not being clearly stated in the research question. It is difficult to formulate a research question which explicitly seeks such a relationship because of the nature of the independent factors, which is highly variant and branched.

As an attempt to answer, or to predict answers to, the previously mentioned research questions, the following null hypotheses were formulated:

- There is no statistically significant relationship between the identified contributing factors and the development of PU among critically ill paediatric inpatients in Jordan.
- There is no statistically significant difference between the predictive validity of the Glamorgan and Braden Q RASs in regard to the PU problem among critically ill paediatric inpatients.

The first two research questions are descriptive in their nature, so no hypothesis was formulated to answer them. In the case of the third and fourth questions, the hypotheses were formulated in the null form to raise expectations regarding the relationship between variables without prejudging the nature or direction of this relationship, and also because this is a format that is statistically testable.

3.3.3 The Study Design

A research study design is a plan made by the researcher which incorporates all methodological decisions that will be adopted during the research process and that will outline the strategies that will be applied to create well organized, accurate and interpretable results (Polit and Beck, 2010). Research design as a part of a quantitative approach usually involves decisions about such issues as whether any intervention or comparison will be made, the type of setting that the data collection will take place within, the number of data collection sessions, and any plan to control the external variables (Polit and Beck, 2010).

This research has involved two major study designs:

A) Study One: A non-experimental cross sectional point- prevalence study.

B) Study two: An experimental prospective longitudinal descriptive correlation cohort study.

Although experimental designs are generally much preferred over other designs in quantitative studies, due to their ability to infer causal relationships, to limit bias through randomization and to control external variables (Polit and Beck, 2010), they are still not applicable to all types of quantitative research.

In this thesis both experimental (incidence study) and non-experimental (prevalence study) designs were used for the following reasons:

- The independent variables (risk factors for PU development) could not be manipulated. Risk factors could be a medical problem or a health condition, such as oedema or obesity amongst others, which could not be changed or unethical to be held such as using sedative or inotropic medications, or the use of some medical equipment such as oxygen probs.

- Experimental design was appropriate for answering the research questions related to the prediction of the two scales performance (ability of the Glamorgan and Braden Q RASs to detect risk in critically ill Jordanian children).

- A descriptive correlation design was more appropriate for investigating the relationship between all identified risk factors and the development of PU because this study is interested in describing the relationship between independent and dependent variables without seeking to establish a causal connection. Otherwise, as mentioned previously, it was unethical and impractical to manipulate independent variables (predicting factors).

- This study is interested in observing the phenomenon (PU development), and describing its different aspects (size of the problem at one point and through time by measuring incidence and prevalence, staging of PU and describing the Glamorgan RAS

in terms of its ability to detect risk of the phenomena in the same population as compared to the Braden Q RAS).

However, there are several disadvantages to using the non-experimental design, the major two being its inability to reveal causal relationships between variables, and the bias created by self-selection. Many nursing studies depend on correlation studies rather than those which seek causal relationships because of the nature of most nursing problems, which are not amenable to experimentation.

Also, the non-experimental design is thought to be more efficient in collecting a large amount of data on one specific problem (Polit and Beck, 2010). In this study, a large amount of data was sought to clearly explore the PU problem in the selected population and to clearly identify significant predictors of PU development in paediatrics, because of a scarcity of such data in this particular population compared with adults.

Self-selection is another negative aspect of conducting a non-experimental study. If the researcher does not randomly select subjects but they are instead chosen for their unique features, this may cause bias in interpreting findings. In such cases, any difference between studied subjects, by chance only, could be a possible explanation of some results rather than the existence of an actual relationship between variables.

For the incidence study of this research work, all the critically ill children who achieved the required number of assessments (not less than two) were included. No specific characteristics were sought and no specific conditions or diagnoses were followed, so as to decrease the bias of the non-randomisation in the sample selection as much as possible. The nature of the study required patients to be assessed more than once (more than the initial assessment) to allow time for the outcome to be accurately detected (PU development). In the prevalence study, however, all children who were inpatients on the day of study, and who matched the inclusion criteria, were included in the survey.

3.3.3.1 Study One: The Cross-Sectional Point-Prevalence Study

Cross-sectional design involves collecting data at one point in time, or multiple points over a short period of time (Polit and Beck, 2010). It was used in this study to collect

data about PU in children across all wards in one hospital in Jordan. The data was collected in one day for all inpatients. This design was appropriate for answering the research question regarding the size of the PU problem among paediatric inpatients in Jordan. It allowed the percentage of affected children at one point in time to be calculated, their characteristics to be described, and the categories of patients' PUs, their sites and their numbers, as well as their original source (either surface or device related ulcers) to be identified.

This design was also thought to be more economically effective and easier for the researcher in terms of managing the data collection and analysis. In addition, it is the most commonly used design in prevalence studies, as mentioned in the literature review chapter.

The shortcoming of this design is the inability to infer results related to changes over time in the studied variables, because these changes might be the result of other external variables such as social or technological factors. However, in this part of the thesis, there was no attempt to infer any relations between the studied variables and the development of PU. The data collected were descriptive in nature, used to describe the characteristics of patients, both those who had PU and who were found free of ulcers on the day of the study. Also, a description of the admission wards was included.

3.3.3.2 Study Two: Non-Experimental Prospective Longitudinal Descriptive Correlation Cohort Study.

A longitudinal study aims to collect data at multiple points in time over an extended period (Polit and Beck, 2010). This design is used to help investigate processes that evolve over time, or to study a phenomenon in which the time consequence is important, in order to compare between two groups of subjects (after intervention, for example). In addition, such a design could enhance the research control, as collecting data before intervention can help the researcher establish initial group differences.

In this study, a longitudinal design was required to examine PU development, which is a medical condition that evolves over time and also to compare the Glamorgan RAS with the Braden Q Scale in terms of the ability of each to predict paediatric patients' risk of

PU development; these children and neonates needed to be followed over time after completing the initial RAS's risk classification.

A prospective correlation design was used to help establish a link between the presumed causes (risk factors / predictors) and the presumed effect (PU development). Also, the prospective design was helpful in measuring the incidence of PU development among critically ill children, because it is a time related problem, and in the follow-up of ulcer-free children, to see if they would develop the problem over time or not.

Initial assessment of ulcer-free children in the critical units was carried out in order to classify children according to their risk score based on the Glamorgan and the Braden Q RASs. Subsequently, a follow up of all assessed children was conducted to identify children who did actually develop PU during the study period. This feature of the prospective design has enabled the researcher to describe the predictive ability of the two scales within the studied population.

Other designs which entail a restricted study time period, such as the cross-sectional design, would not have been useful for answering the related research questions, because of their inability to detect relationships between variables (Polit and Beck, 2010). Prospective design is more costly than the retrospective design, but thought to be stronger as it clarifies the conflict regarding the sequence of cause and effect. For example, this study included an initial collection of data on the assumed contributing factors among ulcer-free subjects, who were then followed over time (8 weeks), and assessed for the outcome, PU development. There was no doubt, therefore, that, any identified risk factors had preceded PU development and not vice versa.

However, the existence of a correlation between variables is not enough evidence that the independent factor causes the dependent outcome (causative relationship), even if the relationship is strong (Polit and Beck, 2010). For example, based on several univariate and multivariate statistical analyses, the results of this study indicated that some factors, such as age being less than one year and a longer length of stay in ICU, had contributed to the development of PU. However, it would be inaccurate to say that these factors had *caused* the occurrence of PU in this group of critically ill patients,

even though they proved to be significant statistically. This is because, in such non-experimental correlation designs, the effects of other covariates cannot be controlled, also, a randomised assignment of sample cannot be established (Polit and Beck, 2010).

3.4 THE STUDY SETTING

This study was conducted at a university hospital located in Irbid, the largest city in the north of The Hashemite Kingdom of Jordan (HKJ), and the second largest city in the whole Kingdom (DOS, 2011). The location allows the hospital to provide primary, secondary and tertiary health care services to more than 1 million inhabitants of Irbid and three other governorates in particular, and to the wider Jordanian population in general.

It is a specialised referral medical centre with 683 beds in several wards, a number which can be expanded to 800 in emergency situations. Usually, it receives advanced cases that cannot be treated at other nearby hospitals, or which would need specialist therapeutic and diagnostic procedures (KAUH, 2011).

This university affiliated hospital contains one Paediatric Intensive Care Unit (PICU) with 12 beds for children aged from 1 month up to 14 years old, which treats medical, surgical and cardiac intensive cases. It also contains one General Intensive Care Unit (GICU) with 12 beds for children aged from 14 up to 18 years old, one General Intermediate Care Unit (GIMU) with 10 beds for neurosurgical patients) which both admit children, and finally one Neonatal Intensive Care Unit (NICU), which include 24 beds, for babies from birth up to 1 month old (KAUH, 2011).

For this research work, the hospital was chosen conveniently, however, many reasons could justify that. This hospital is the largest in the north, and has many specialist paediatric units, including a neonatal ICU, paediatric and general ICUs, medical and surgical paediatric wards including orthopaedic and oncology wards, cardiac and neurosurgical ICUs and intermediate care units.

The nature of the incidence study and the need to collect risk factors, in addition to the description of the risk assessment scales, necessitated choosing a hospital which

contained as many critical care wards as possible which could be included in the study, so as to attain a larger sample size and thus generate more reliable data.

The use of the computerised record system (MEDICOM) greatly assisted in establishing and recording much of the required data. The system eased the researcher's access to each child's current and previous medical records, laboratory test results, and some demographical characteristics throughout the study period.

This study was carried out in one hospital only because it was necessary that the children who took part were assessed frequently, and, due to the absence of an assessment team, the researcher would not have been able to assess children in two different locations. The choice to work individually without the support of a team or other nurses was made for the following reasons:

- It was important to gather reliable data and, if assessments were being performed by a number of different nurses or investigators, the data may not be comparable. Also, the subjective grading of PUs may affect the reliability of the findings.

- There is a lack of information regarding PU in children among Jordanian nurses since pressure ulcers are still thought to be an adult only problem. The researcher needed to establish baseline data to convince Jordanian health care personnel that PU exists in paediatrics, before any training or teaching sessions could be held.

- Because it is a phenomenon which has only recently been brought to light in Jordan, nurses lacked the motivation to participate in collecting data regarding PUs, especially ICU nurses who preferred to spend their time and effort focusing on what they deemed to be more serious physiological issues, such as airway clearance, respiratory support and so on.

- There was a lack of time and resources available to conduct training sessions for the nurses or researchers who would have been required.

In addition to the reasons already given, no previous study regarding paediatric PU prevalence and incidence had ever been conducted in Jordan which meant that any large, representative hospital would have been suitable for the study.

3.4.1 Jordan and its healthcare system

Before detailing further the dimensions of the research sample and procedures, a brief description of the country where the research was conducted is provided.

Jordan is a small country located in the Middle East; its formal name is the Hashemite Kingdom of Jordan. Excluding the coastal border on the Aqaba Gulf, land borders Jordan in all directions (Figure 3.1). Neighbouring countries are Iraq, Syria, Palestine and Saudi Arabia, with which Jordan shares its longest border. The total area is 92.300 km², of which land makes up 99.6% (91.971 km²), and the remaining 329 km² is represented by the Aqaba Gulf and the Dead Sea, which is the lowest point on Earth (Central Intelligence Agency (CIA), 2009).

The last estimation made by the department of statistics (DOS) revealed that the total population was 6,181,000 (DOS, 2011). Islam is the official religion of the country and Arabic is the official language, but English is widely used in certain sectors, such as trade, education, health, and government and banking.

- ***The healthcare system:***

The Jordanian healthcare system is one of the leaders in the region, and has a good reputation in the Middle East (Library of Congress, 2006). According to the Ministry of Health (MOH) in Jordan, the government spent about 7.2% of gross domestic product (GDP) in 2008 on healthcare (MOH, 2008), which is close to the international average of 9.3% (Library of Congress, 2006).

The total number of hospitals, either public or private, in Jordan is 103. The public sector has three divisions. The first is the Ministry of Health (MOH), which runs 30 hospitals comprising 38.7% of the total number of Jordanian hospital beds. The second is the military's Royal Medical Services which operates 11 hospitals, and represents 19% of the total number of beds, while the third is made up of two university affiliated

hospitals, which manage 9.2% of Jordanian hospital beds. In addition, the private sector runs 60 hospitals, which contain 33.1% of the total number of beds (MOH, 2008).

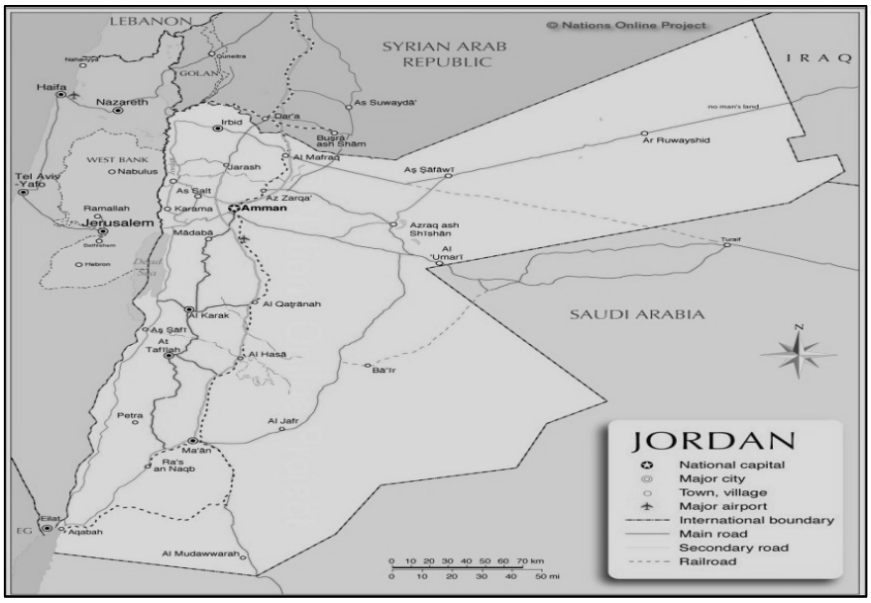

Figure 3.1: Jordan Map

3.5 THE STUDY SAMPLE

The target population of this research was paediatric inpatients in the aforementioned hospital. The sample, a select portion of the whole population (Polit and Beck, 2010) was recruited differently in the prevalence and incidence studies. In general, sampling designs fall into two categories: probability and non-probability sampling. The first of these involves randomly selecting subjects from the population, while in the second the subjects are selected by non-random methods. Probability sampling is generally the more respected of the two approaches because greater confidence can be placed in the sample's representative nature (Polit and Beck, 2010). However, non-probability sampling was used in both parts of this study, as explained below;

3.5.1 The Prevalence Study Sample:

The prevalence study sample was a non-probability convenience sample of all paediatric inpatients that were present in the hospital on the day of the study. All children aged from birth up to 18 years old on the day of the survey were included.

This sample was conveniently selected because of the nature of the study, and the research question of inquiry, since the main goal was to estimate the size of the problem among Jordanian paediatric inpatients, so recruiting as many children and neonates as possible would ensure a more representative sample of the studied population. Using a probability sampling method would have restrained the sample size, since randomization excludes many participants from being recruited in the study.

In addition, randomisation in selecting the wards would have increased the risk of selecting unwanted specialities such as adult patients, or emergency patients. Above all, however, randomisation would have minimised the number of patients in the sample, making it difficult to derive meaningful estimates by some statistical analyses, thus affecting the generalisability of the findings to other paediatric populations.

Inclusion Criteria:

- Being a peadiatric patient aged from birth up to 18 years old.
- Being an inpatient in any of the paediatric wards in the target hospital (critical care units, medical-surgical units, orthopedics, oncology and neonatal wards).
- Verbal/ written consent being given (by children age 10 years or older, if applicable, and by their parents or guardians).

Exclusion Criteria:

- Patients who were 18 years of age or older on the day of the survey.
- Being a child or neonate admitted to psychiatric, isolation or burn units.
- Children in the daily case unit, emergency unit and outpatients' clinics. (These wards do not require children to be in hospital for more than 24 hrs, whereas the study looked at PU development among inpatients in the hospital).

There are a number of reasons why working with paediatric patients admitted to psychiatric or isolation units may not have been sensible for the researcher on this occasion. Dealing with patients in isolation units may unintentionally break sterility circles, which may lead to the spread of nosocomial infections to children in other units. Furthermore, working with psychiatric patients would usually require special proficiency and experience, and extra training, since a lack of knowledge and skills about how to treat such patients might increase safety hazards, for both the child and the researcher. Also, children admitted with a psychiatric primary diagnosis would not normally have physiological problems at the time of admission.

Likewise, special expertise would be needed to assess the skin of children in burns units for PU existence, because of the nature of their condition. The skin may be, for example, oedematous, lacerated, reddened or oozing and therefore this group were excluded to decrease the chance of false negative or false positive PU findings. Also, direct skin contact with these patients, who have large surface areas of damaged skin, makes them more vulnerable to infection.

The prevalence sample was composed entirely of children and neonates who were admitted to all the paediatric wards in the target hospital, and who had met the inclusion criteria, on one day in November 2010.

3.5.2 The Incidence Study Sample:

This sample was obtained by means of ‘consecutive non-probability sampling’. This type of sampling involves recruiting all available subjects from a specific population, and who meet the inclusion criteria, over a specified period of time, or until a specified sample size is reached (Polit and Beck, 2010).

For this study, critically ill children were the target population. This was because of the considerably high risk of these children compared with the general paediatric

population, as mentioned earlier in the literature review chapter, and also because the findings from the prevalence study showed that PUs were particularly prevalent in the children who were admitted to critical care units.

Moreover, limiting the target population in this way meant that fewer resources and less time were needed to answer the research questions. Because the nature of the study required frequent skin assessments to be carried out by the researcher over a long period of time, it would have been more difficult to conduct in all of the general paediatric wards in the hospital.

Over a five month period, all paediatric patients who were admitted to the critical care units, and who were eligible to participate, were recruited. Every eligible child in the target population was recruited for the study until the researcher had achieved the target sample size, which was over 200 patients, and more precisely over 194 patients according to the power analysis.

This consecutive method of sampling was thought to be superior to the convenience sampling method, since all the subjects of the target population would be invited to participate in the study over a specified period of time. It was believed that this would greatly reduce the risk of convenience sampling bias (Polit and Beck, 2010).

In summary, the sample for the incidence study was composed of all paediatric inpatients admitted to the critical care areas (GICU, PICU, GIMU, and NICU) of the target hospital between November 2011 and May 2012. Children had to be initially assessed within 24 hours of being admitted to the wards to ensure they had been free from PU on admission. All children who were found to have PUs during this assessment were excluded from the survey.

Inclusion Criteria:

- Being a newly admitted paediatric inpatient to one of the previously mentioned critical care areas (within the first 24 hours).
- Being a critically ill child/ neonate aged from birth up to 18 years old on the day patients were recruited for the study.
- Being admitted to one of the critical care areas: GICU, PICU, GIMU, or NICU.
- Being free of PU during the initial skin assessment (assessment no. 0).

Exclusion Criteria

- Being admitted to psychiatric, isolation or burn units.
- Being admitted for less than 72 hours.
- Having a skin assessment carried out less than twice during their current admission (the nature of the study required more than the initial assessment of the child's skin to allocate the tracked outcome which is PU development).
- Being a child or neonate with PU on initial assessment (within 24 hours of admission to the unit).

3.5.2.1 Sample size:

Deciding on an appropriate sample size is one of the important steps a researcher should take before collecting data. It is a crucial part in the research process, because of its major effect on research findings. A small sample may underestimate the actual relation the researcher might seek while looking for a specific explanation for a relationship between variables. However, studying a large sample is not always an option for researchers as it may be too time consuming and costly. Power analysis is a procedure which is often conducted by researchers to estimate the required sample size for a study (Polit and Beck, 2010).

There are three main criteria required by a researcher to determine the sample size through power analysis: α, the significance criterion; e, the population effect size; and *P*, the power (1- β, where β is the probability of *type II* error). In this study, α (the risk of Type I error) was specified at 0.05. This level of significance was chosen as it is usually used in nursing studies, and because of the nature of the variable under investigation, which is not a life-threatening condition and therefore does not necessitate a smaller significance criterion. The power (1- β) was established as 0.80, and the population effect size as medium (0.3) (Cohen, 1992).

A medium effect size (0.3) was set to be investigated as this is the norm in many nursing studies and since the effect between variables sought in this study did not relate to rare or life threatening conditions. A large effect size (0.5), which would require a smaller sample size, may have weakened the findings of the study by being under-representative of the studied population. Using a larger sample in searching for a small effect size (0.1) would also have been difficult to achieve because it would have been costly and time consuming for the researcher.

The G*Power 3 software (Faul et al., 2007) was used in this study to estimate the sample size using the previously mentioned values. By applying *a priori* power analysis using the *LR* test, the required sample size was found to be 194 subjects. Taking into consideration, that the following values, were used: one tail, *OR* = 1.8 'the minimum detectable odd ratio', and *Pro* = 0.1 'the proportion of cases in total sample'. These values were proposed based on those used in previous related literature.

3.6 STUDY INSTRUMENT

The study instrument is a tool used by the researcher throughout the research process to address the problem in hand and collect the relevant data (Polit and Beck, 2010). A new tool – the Data Collection Sheet - was developed for this study. The tool was composed of two parts, one related to prevalence study data, and the other related to the incidence study (Appendices 3.1 and 3.2).

The instrument was developed based on a thorough investigation of the data related to adult and paediatric PU development in previous literature. The demographical data section was adopted from previous relevant PU incidence and prevalence studies, and aimed to include as many patient characteristics as possible.

The pressure ulcer prevalence rate was calculated by dividing the number of patients with PUs by the total number of assessed patients on the day the audit was conducted (Suddaby et al., 2005, McLane et al., 2004, Groeneveld et al., 2004a, Willock et al., 2000). A specific section was provided on the tool to document findings related to PU

existence, categorising the severity of ulcers based on the EPUAP PU classification systems (EPUAP and NPUAP, 2009), and recording the location and number of PUs.

Furthermore, the general characteristics of the prevalence sample were recorded so that they could be used later in comparing the PU group with the PU-free group of patients. Such characteristics included age, gender, LOS in hospital, and primary medical diagnosis.

In the incidence study, the incidence rate was calculated by dividing the number of patients who developed PU during the follow-up period (8 weeks) over the total number of PU-free patients who were recruited at the beginning of the audit (Willock et al., 2000). Information on the severity, location and number of PUs was provided. As in prevalence part, the categorisation of ulcers was based on the EPUAP PU classification system (EPUAP and NPUAP, 2009).

A specific section of the tool was designed to investigate any defined risk factors that were detected in the incidence sample. These factors were collected from previous adult and paediatric PU risk studies. Paediatric PU-experts' opinions and the supervisory team's views were also sought in determining the relevant predictors of PU development in this particular population. The last two sections of the incidence part of the tool included the Glamorgan and the Braden Q RASs.

3.6.1 The Prevalence Tool

This data collection tool consisted of two main sections as follow:

- ***Section A):*** Included data related to the ward, such as type, number of beds, and number of admitted patients. It also included the following patient characteristics: first name, file number, medical diagnosis, date of admission, and LOS in hospital, as well as, age, gender, and date of birth. If a patient had had previous hospitalisations was also recorded.

- ***Section B):*** Included data about PU existence (Yes/No), and, if present, details about the ulcers, such as number, category based on the EPUAP classification system (EPUAP and NPUAP, 2009), location, and home or acquired.

3.6.2 The Incidence Tool

The incidence study tool consisted of five main sections, A, B, C, D, and E, These included the following sets of data:

- ***Section A):*** included data related to the ward type, and the patient's demographical characteristics, such as, identification number (ID), file number, age and date of birth, gender, newborn gestational age, medical diagnosis, previous hospitalisations, ICU LOS, and date of admission. Also, data related to height, weight, and the vital signs (O2 saturation, blood pressure, heart rate, respiratory rate, and temperature) were added.

- ***Section B):*** included data about any PU developed during the follow-up period, which is explained thoroughly in section 3.8, the study procedures. The details recorded were the number of the newly located ulcers, their sites and categories. Also, these ulcers were documented in specific tables in the tool, to clarify the exact date on which they were first observed. A further table was added after the pilot study was conducted, to document the date and outcome of each skin assessment, the initial and the follow-up.

- ***Section C):*** this part included all the pre-determined possible risk factors that were planned to be collected during the incidence study, such as laboratory test results, type of medications administered, medical devices used, skin condition, whether or not the patient was on MV, whether paralysis existed or not, and consciousness level. Most collected Risk factors were in the form of checklist, when applicable, for easier and faster work.

A special table was added after the pilot study was completed to document the medical devices being used, their type and number for each patient.

- ***Section D):*** this part of the tool was filled in on the day of each patient's admission and it includes the Glamorgan RAS.

- ***Section E):*** the final part included the Braden Q RAS. This was also completed on the admission date, as soon as the researcher conducted the skin assessment for each patient at their bedside. For a summary of data collection sheet' sections see (Figure 3.2) below.

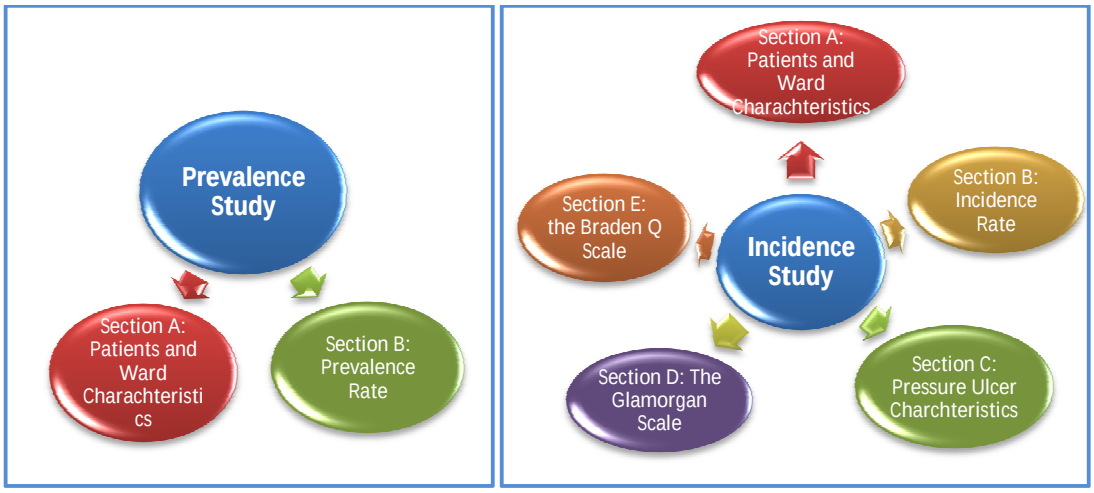

Figure 3.2: Two Data Collection Sheets: Incidence & Prevalence.

3.6.3 The Glamorgan Paediatric Pressure Ulcer Risk Assessment Scale

This scale was developed in 2007 by means of comparing the characteristics of children with PU with those who did not develop PU, and testing the significance of the existing relationships statistically. Further amendments were undertaken in 2008, following an inter-rater reliability study of the newly developed scale. Based on the results of the study, the nutrition sub-item was enhanced by the addition of several indicators of risk in children (Willock et al., 2008).

The final version of the scale has nine sub-items (Appendix 1.10), with varying weightings of the sub-scores for each item. The highest sub-scores were given to *immobility* and *equipment pressing or rubbing on patient skin* conditions, with a range between 10 and 20 depending on the condition's severity, while the remainder of the scale's sub-items scored 1 if they were found to exist and 0 if absent or not measured.

The total risk score ranges from 0- 42, where ≥10 indicates 'risk', ≥15 'high risk', and ≥20 indicates 'very high risk' patients.

The main terms used in the Glamorgan RAS, along with its related definitions and risk scores are based on special guidance on using the Glamorgan scale, which has been provided by the scale's developer (Appendices 3.3 and 3.4).

The Glamorgan Paediatric Risk Assessment Scale (Glamorgan RAS) was chosen for this study for the following reasons:

- It is a newly developed scale for paediatrics which, according to the authors, needs to be tested within new settings and different populations. In this thesis, the scale was tested among a new set of children, namely those who are admitted to critical care units.

- It is the first paediatric RAS which depended on statistical testing of patient data. Other paediatric RASs have either been developed from patient observations, expert opinions or have been modified from adult RASs (Willock et al., 2009, Barnes, 2004, Willock and Maylor, 2004).

- The scale appears to be a promising tool, since it was found to have higher predictive validity compared with other paediatric RASs, even with scales that are frequently used in paediatric; such as the Braden Q scale (Willock et al., 2009, Anthony et al., 2010).

- This scale is the only one in paediatrics that recognises the effect of 'equipment pressing or rubbing on the skin' explicitly as a sub-item while giving it a high risk score on the scale. Although there is a newly developed scale, the Braden Q+ P scale (Galvin and Curley, 2012), that names any device attached to patient skin as a category of risk, this was developed only for OR patients. Also, another scale developed by Barnes (2004) lists splints and casts, as well as monitors cables, as risk factors for PU development in children but there is no further mention of other equipment.

This criterion is important for this study as many authors have pointed out that children's pressure areas are greatly affected by the use of medical equipment, especially in ICUs (Suddaby et al., 2005, McCord et al., 2004, Zollo et al., 1996). Problems may include tubes pressing or equipment rubbing on children's skin, and lying for long periods over tubes or even on needle caps, in addition to the folds of the bed linen (Zollo et al., 1996, McCord et al., 2004).

3.6.4 The Braden Q Pressure Ulcer Risk Assessment Scale

This tool was developed in 1996, based on several modifications of the adult Braden scale. As discussed thoroughly in the literature review chapter, the modifications included the addition of a new sub-item (tissue perfusion and oxygenation), and new indicators to clarify existing ones (such as adding Albumin level to the nutrition descriptors).

The scale is composed of seven sub-items: *mobility, activity, moisture, tissue perfusion & oxygenation, friction and shear, sensory perception and nutrition*. Each sub-item has a score range from 1 to 4, with four being the most favourable and one indicating the worst cases. The total score for each child should range between seven (the highest risk) and 28 (where there is no risk at all) (Quigley and Curley, 1996).

The main terms and categories of the Braden Q RAS, with their related definitions, as used in this research, were based on Noonan et al. (2011). These are presented in (Appendix 1.9).

The Braden Q RAS was chosen for this study for the following reasons:

- It is thought to be a valid and reliable paediatric-specific PU RAS (Noonan et al., 2011).
- It is the most widely used paediatric PU RAS that has been found or discussed in paediatric literature (Loman, 2000, Curley et al., 2003b, Noonan et al., 2006, Suddaby et al., 2005, Noonan et al., 2011). Also, many paediatric

studies used the original Braden Scale (Samaniego, 2004, Schluer et al., 2009).

- The authors recommend to test this scale with different samples and in different settings. Studies should include children of more diverse age groups and not exclude children with certain conditions such as congenital heart diseases (Curley et al., 2003b, Noonan et al., 2011).

- Taking confidence intervals into account, it was the first scale that tried to define a cut-off risk score based on experts' clinical judgment (Loman, 2000).

3.7 THE PILOT STUDY:

A pilot study, sometimes called a 'feasibility study', is a small scale version or a trial that usually precedes the major study to ensure that the proposed research methods are applicable (Polit and Beck, 2010). Piloting or testing the researcher's data collection tool or intended interventions helps determine their acceptability by subjects, or by other investigators, and also allows the researcher to consider the cost and ease of the planned research procedures (Parahoo, 2006).

The responses the researcher may get from such a trial help him or her to improve the methodology and the research tool. They may also notify the researcher of any errors, ranging from typing errors to much more serious problems that could affect the structure or the proper functioning of the tool (Parahoo, 2006).

For this research, the data collection tool was sent to a small group of PU experts and research colleagues (n=4), one of them with particular experience in paediatric PU. The responses and feedback received helped in improving the tool in the following ways: any identified errors were corrected and any part that was unfeasible in the clinical fields was restructured, the section contents were changed to include more paediatric suitable information, and the format of the tool was amended based on whether it was considered easy to fill in and follow in practice.

In addition, an inter-rater reliability test between the researcher and a paediatric PU expert was performed, to ensure reliable categorising of the identified PU grades during the actual survey. The researcher assessed 10 PU photographs and categorised them according to the EPUAP classification system as PU categories 1-4, erythema, and moisture lesion. The researcher's assessments were then compared to the expert assessment and inter-rater reliability was determined using the percentage of agreement and Cohen's Kappa. The Kappa calculated for this study was 0.872 ($p<0.001$), and the percentage of agreement between the researcher and the expert was 90%; both indicated an excellent agreement.

Before the actual incidence study was conducted, the researcher also applied the tool to a small group of children (n=5) admitted to one intensive care unit (i.e. PICU). The tool was filled in for each child in one day, a week prior to the commencement of the main data collection period. The gap of one week was chosen to allow sufficient time for the researcher to conduct one more follow up visit to these patients.

The aim of the follow–up visit was to identify any obstacles the researcher may encounter in the follow-up process, and to assess the ease of accomplishing it. The visit was also an opportunity to gauge the accessibility of the hospital computer system for obtaining patients data, and to estimate the time period the researcher would need to perform the assessment on existing patients, while looking at the same time for new recruits. The one day follow-up was not intended to perform an actual assessment of the development of PU. Children in the pilot study were not included in the actual incidence sample or in the statistical analysis.

The researcher assessed the ease of completing the tool, and documented notes on any data for the children that were inaccessible. This helped to underline any obstacles which may have to be confronted as the children's skin assessments were carried out, or the need for modifications to any section of the tool. In short, the implementation of the tool on this small scale gave the researcher an overview of the advantages and disadvantages that could be encountered during the actual data collection.

The PICU was selected as the site of the pilot study because of the variety of children of different ages, including neonates, infants, and older children, who would be admitted.

Based on what has been outlined above, after the pilot study, the following amendments were made to the data collection sheet:

- The prevalence and the incidence data were separated onto two different data collection sheets (Appendices 3.1 and 3.2); this was for ease of collecting data and managing information, since the studies involved two different samples of patients, measuring different areas, and they were separated by more than one month.

- In the incidence tool, a follow–up table was added, with 12 columns to show the maximum number of follow-up assessments and two rows indicating the date of assessment and the outcome of the assessment (PU developed or not).

- Another table was inserted which would be filled in if any PU was observed. This table included the PU's characteristics, the date it was first observed on, and the reason for the child's participation in the survey being discontinued.

- A special table was added to document any existing medical devices, by ticking the type, and writing the number of devices in the relevant space.

- Certain variables, such as ABGs, and PEEP level were added; because of their necessity, mentioned in previous literature, as risk factors for PU occurrence, in ICU patients.

- Certain variables were omitted because of their inapplicability to the paediatric sample. These were, firstly, the presence of the 'do not resuscitate' order (DNR), which none of the children in the studied units had, since it is mostly used for adults in this hospital but not in paediatrics; secondly, paralysis, omitted because it would be covered by the 'mobility and activity' sub-items of the two scales used; and thirdly, malignancy; which was not observed in any child case during the data collection period.

3.8 **DATA COLLECTION PROCEDURES:**

Data collection was conducted on two separate dates, with one month in between, for the two independent studies which formed this research (prevalence and incidence). Each one is explained separately below. The data collection was accomplished by one rater, the researcher. Many studies have shown that the number of raters seems not to affect the prevalence rate (Kottner et al., 2009a, Kottner et al., 2009b). In fact, the author believed that the quality of the researcher's training is more important than the number of the raters involved in assessing PU (Kottner et al., 2009b).

Furthermore, having only one rater conduct the study was thought to be beneficial in terms of improving reliability, by decreasing the variation that could exist if more than one rater was used. The use of a sole rater would improve consistency in reporting the existence of PUs, their numbers, sites and categories. Also, it is not unusual to have one rater in PU incidence and prevalence studies (Kim et al., 2009, Chan et al., 2009).

3.8.1 The Prevalence Study:

Initial preparations took place before this part of the study was carried out, to ensure an appropriate allocation of time and resources. On the day of the study, the researcher requested a list of all admitted paediatric inpatients aged from birth up to 18 years and this was provided by the information technology department (ITD) of the hospital. The included wards were surveyed sequentially, based on their level in the hospital, starting with the lower ground up to the highest floor level.

Each floor had four wards, each was visited as applicable, depending on the admitted cases. Any child who was not available at his or her bedside at the time of visiting the ward was excluded from the study, although, in fact, this criterion only resulted in one child being excluded.

After ethical approval was obtained from the target hospital (Appendix 2.2), the survey was conducted over one day. On this particular day, the researcher completed the physical assessment for the skin of each eligible child (as per the criteria mentioned earlier). This took place at the bed side, in no longer than 10 minutes. Consent forms were obtained from parents (Appendix 2.9), and from children (Appendix 2.11)

according to their age groups as applicable. Verbal consent was also taken immediately before the assessment was started, to ensure that the child and parents understood the study, and still agreed to participate.

The skin assessment involved examining the entire skin, and especially the areas which, according to previous literature, are the most severely affected (head, especially occiput and face, sacrum, heels and a long side any attached medical devices to the child skin). The researcher carried out the assessment in the presence of the child's bedside nurse, to assure that the patient's and researcher's rights were preserved. Also, the nurse was able to help with repositioning patients if this was difficult for the researcher to do alone, either because of the child's weight, or due to the existence of complicated medical equipment being in place.

The categorisation of PU-cases in this study was based on the EPUAP classification system (2009) (Appendix 1.7). After each assessment was carried out, the researcher completed the sections of the prevalence data collection sheet. Data documented for each child included general information about the ward, patient demographics, and the characteristics, number, category and location of each identified pressure ulcer. These details were recorded immediately to reduce the possibility of missing or inaccurate data documentation. Other data were derived from patients' hospital files (medical records) as needed, before the skin assessment was initiated.

3.8.2 The Incidence study:

This study' data were collected over five month's period from December 2011- May 2012, with a follow-up period of up to eight weeks. This time period was chosen based on the findings of other relevant PU incidence studies. One study which was carried out in three PICUs revealed that most ulcers developed in the first two days after admission (57%, n= 113), and all except one of the identified ulcers had developed before day eight (Curley et al., 2003a).

Another multi-site incidence study which was conducted in neonatal ICUs revealed that the vast majority of PUs had developed in the first 21 days following admission (78.6%,

n= 11) and, of these, six developed within the first week (54.5%) (Fujii et al., 2011). One more incidence study of PU in adult patients observed that more than 80% of the developed ulcers had occurred in the first 40 days after admission (n= 36). Of these, around half developed within the first 20 days (40.1%, n= 18) (Onigbinde et al., 2012).

Children who had been admitted to the hospital's ICUs (PICU, NICU, GICU, and GIMU) were included in this incidence study. Any child admitted to the ICU on the intended date of study was included and was examined within 24 hours of their admission, a protocol which has been shared by several previous PU incidence studies (Curley et al., 2003a, Chan et al., 2009, Kim et al., 2009).

Within the first 24 hours of a child's admission to one of the previously mentioned ICUs, the researcher conducted an initial skin assessment (no. 0). This assessment helped the researcher in:

- Detecting the presence or absence of PU, taking into consideration that any child who was found with PU at the initial assessment was to be excluded from this study.

- Collecting demographical and general data. This also depended on gathering data from patients' files, and extracting laboratory test results from the hospital's computer system.

- Recording details of any presumed predictors of patients' risk of developing PU during an ICU stay.

- Calculating the risk score for each child of developing PU, by employing both the Glamorgan and Braden Q RASs. This subsequently aided in classifying children into 'risk', 'high risk', 'very high risk', and 'no risk' groups according to the Glamorgan scale, or into 'risk' or 'no risk' groups according to the Braden Q scale.

For each child to be included in this study, he/she needed to have at least one follow-up skin assessment after the initial assessment, to allow time to address any changes in the child's skin condition (i.e. the development of PU). Therefore, the total number of assessments carried out ranged from 2 to 12, including the initial one (no. 0). The first

week of the child's stay would include three skin assessments on fixed dates (no. 0; the first one in the day of admission, no.1, on the third day following admission; and no. 2, the third one, held on day number seven).

The second week included three similar assessments (nos. 3, 4, & 5), and then weekly assessments were conducted until the patient died, was discharged from the ICU, or the follow-up period finished without PU developing (up to 12 assessments by the end of week eight). This protocol of setting out when the assessments would occur was adopted from a similar study by Curley et al (2003b). This particular study was thought to be the most relevant to the current work since it was implemented in PICU. The timescale for assessments was also based on previous literature which recommended carrying out the initial skin assessment within the first 24 hours (Curley et al., 2003b, Chan et al., 2009).

In addition, on the recommendation of other relevant studies, the initial assessment was conducted within 48 to 72 hours of admission (Reddy, 1990, Quigley and Curley, 1996) seeing as the second assessment (no. 1) subsequent to the initial admission assessment (no. 0) was performed on the third day following the child's admission to the ICU.

Each of the studies cited above has claimed that the time between the cause and the actual appearance of PU is up to three days. However, even in the adult literature, there is no agreement about the best date to detect PU, especially those categorised *I*, although it is generally thought that a PU of category *II* or higher, would take three to five days to develop until it could be observed on the skin (Lindan, 1961, Reddy, 1990, Dinsdale, 1973).

In this thesis, the majority of PUs were observed during the first observation day following the initial assessment (42%, n=8) and the vast majority of PU-patients had developed ulcers by the first and second observations (73.7%, n= 14), thus data collected during the initial observations were used to compare the PU- and PU-free patient groups. Similar findings were noted in (Curley et al., 2003b), in which data was analysed based on the first observation, where 57% of ulcers were observed.

The skin assessment was a complete assessment of the child's skin from head to toe based on the researcher's judgment with the naked eye. The outcome the researcher was interested in throughout the frequent assessments was whether the child would develop PU or not.

Even when it was noticed that a child had developed PU before the end of the follow-up period, the assessments were continued, so that any changes in the developed PU (for example, its category or any healing) and/or the development of further PUs could be recorded.

Any PU observed during the study was documented with details of the ulcer's category, location and numbers. If an ulcer was found covered with Eschar, it was considered category *IV*, as recommended by the EPUAP (EPUAP and NPUAP, 2009).

By the end of the initial skin assessment the researcher had completed all the sections in the incidence data collection sheet, except for section B (PU characteristics table and follow-up assessment table) which was filled in on the first day, and continued to be throughout the follow-up period.

3.9 ETHICAL CONSIDERATIONS

Ethical approval for this study was obtained from the ethics committee of the Faculty of Health and Life sciences at De Montfort University in 2010 (Appendix 2.1). In addition, approval was received from the Ethics and Research Committee of the target hospital in which the study took place in Jordan (Appendix 2.2).

For the prevalence survey, participant information sheets (PIS) and consent forms (CF) for both the parents and children - when applicable - were given to the target population before the study commenced (Appendices 2.3-2.12). Each participant was allowed a few hours to decide if he or she would like to participate, while the researcher spent time distributing the consents and information sheets in other units, before returning to start the assessments with those who agreed to participate. This time allowed participants and their parents/guardians to take their decision freely without feeling that they had been rushed to do so.

For the incidence study, consent forms and participant information sheets were given to each child or their parents on the day of the assessment, as soon as the patient was admitted. Though, in most children cases, CFs were obtained from parents only, because of the acute condition of these children when admitted. Time to read the PIS and the CF was allowed before the actual assessment was carried out. A verbal explanation of the study's aims and procedures was given and verbal consent was sought, immediately at the time of assessment, in addition to the consent form.

The confidentiality and anonymity of all participants was ensured throughout the study. Participants' names were not taken in full; instead, each participant's first name only and his/ her file number were used together to identify patients and access their files and information, with minimal chance of error. The files all were used restrictively by the researcher only.

Children and parents were assured throughout the entire study that they were free to withdraw at any time without any obligations or penalties, and their children's rights and safety would be protected before, during and after the study took place. This was a realistic possibility in this study because the researcher would need to inspect the child's entire body, which may cause embarrassment for the child, perhaps especially if he/she was adolescent. The need for a complete physical assessment of the child's body was, however, highlighted in the PIS.

3.10 **STATISTICAL ANALYSIS PLAN**

Data were analysed using the SPSS version 17 (SPSS, 2008). Both descriptive and inferential statistics were used in this study. Descriptive statistics, including frequency distribution, central tendency measures, variability and correlation statistics, are used by researchers to formulate and describe sets of data. On the other hand, inferential statistics are usually used when a researcher is more interested in inferring conclusions about the population by using data from the sample. In such cases, the researcher is interested in building assumptions and testing hypotheses rather than in simply describing variables or phenomena (Polit and Beck, 2010).

Descriptive analysis was performed for the demographical data using the median and range for the categorical variables, whereas mean and standard deviation (SD) were used for continuous variables. Moreover, descriptive statistics using percentages and frequencies were used to summarise all the demographical variables, the ward characteristics, and to calculate the overall prevalence and incidence rates. In addition, they were used for calculating the number of skin assessments, number of ulcers and the most affected areas.

Inferential statistical tests also were used depending on the nature of data. The study sample was divided into two groups: PU-patients and PU-free patients. *The chi-square* test *(X^2)* was used for categorical variables, to examine the difference between patients with PU and those free of ulcers in ICUs. For the same groups, the relationship between IVs (risk factors / predictors) at least in ordinal level and the DV (PU development or not) were tested using the *Mann–Whitney U-test*. On the other hand, variables with at least ordinal level, and which were normally distributed, were measured using the *independent t-test*. In fact, this test was used only once for assessing the relationship between the serum potassium level (*K*) and PU development. Testing for normality was carried out using the *Kolmogorove-Smirnov Z* test on the SPSS.

Four *LR* models were built to examine the significance of the relationship between the predictors of PU (risk factors/ IVs) and its development (binary DV/ outcome). These four models were established to make it easier for the researcher to deal with different types of risk factors - general or scale sub-items - as well as to avoid redundancy in testing closely related variables, such as in testing the mobility sub-item in each scale.

For example, as will be seen later in the results chapter, models one and two dealt separately with the Braden Q scale sub-items and the Glamorgan sub-items. The third and fourth models were created to test the relationship between the general identified risk factors, and the Braden Q, as well as the Glamorgan significant sub-items, each in turn. Also, the four models were created to identify the significant sub-items of each risk assessment scale, while considering the *OR* for each sub-item, and for the scale's total risk score.

The predictive validity of the Glamorgan and the Braden Q risk scales was tested by using the ROC curve through calculating the AUC for each tool, and then for each sub-item of each scale, this indicated which variables of each scale could be removed, enhanced or changed to improve the overall predictive ability and performance of the scale. The AUC, sensitivity and specificity of each scale were specified by different cut-off points; this helped in comparing the effectiveness of performance and classification ability of each scale.

3.11 **THEORETICAL FRAMEWORK REFLECTION ON THE RESEARCH METHODOLOGY:**

The theoretical framework used in this research focuses on the same areas of interest in this research; the main two hypotheses in this research concerned the identification of significantly related risk factors to PU development in a particular population - namely, the paediatric ICU patients- and the comparative performance of two tested scales regarding their ability to detect PU risk. The aim of gaining a full picture of children's risk in regard to PU development prompted this thesis to search for truly related risk factors. It was hoped that these risk factors could be found by conducting a reliable and valid study with evidence based results.

SDT proposed that any observer should be able to detect the true signal when accompanied with other noise. Applying this proposition to nurses, it would be each nurse's responsibility to identify the true risk factors of PU development in children, and to differentiate these factors from other unrelated factors. Having statistically significant predictors of PU with which nurses are familiar, would help them to identify risk children correctly as soon as they were assessed.

Moreover, this theory explained how each observer, or scale used by an observer, should have a criterion upon which the observer or scale can be classified as being specific and sensitive in detecting the true signals. In this research, the nurse's ability to use the Braden Q and the Glamorgan scales is based on a specific criterion which classifies children as being at risk or not, or, in other words, the cut-off score for each

scale. Also, the study aimed to measure the sensitivity and specificity of each scale's cut-off scores (the criterion).

So, this study tried to test the predictive validity of each scale based on their respective cut-off scores, with the aim of identifying the most valid tool as applied to the data presented by this sample. Having a valid RAS would also improve the observer nurse's ability to detect risk and classify at-risk patients correctly. Identifying children who are at true risk would help in allocating health resources properly, saving time, money and effort, by applying prevention strategies for those who are truly at risk.

Based on the theory, identifying all possible risk factors correctly would minimise false predictions among children who are not risk (false alarms / false positives) and to truly identify children who are at risk of PU (hits / true positives). Yet, in reality this cannot be assured one hundred percent. However many true risks factors of PU development are identified, it is still not possible to specify all potential predictors with complete confidence. Continuous progress in the medical fields and improvements in technologies being used, along with the increasingly complex and variant nature of children's illnesses, causes the constant appearance of new obstacles and hazards.

This study has used the SDT main themes to help nurses to identify valid risk factors of PU development among paediatric ICU patients. It has also offered them a valid tool for detecting PU, with relatively accurate cut-off scores, to predict their paediatric patients' risk whatever their condition, age, or surrounding circumstances was.

3.12 SUMMARY OF THE CHAPTER

This chapter aimed to report the research processes that were undertaken throughout the course of this study, covering issues related to the research design, research questions and hypotheses, appropriate sampling plan, research procedures and statistical plans.

Ethical considerations were also underlined to ensure that the data collection plan was accomplished, while at the same time the participating children's rights were protected, and any applicable risks were minimised.
Figure 3.3 is a model of the methodology used for this research work.

Figure 3.3: Model of Research Methodology

CHAPTER FOUR:

RESULTS

4.1 A GLANCE AT THE CHAPTER

This chapter discusses the results of the statistical analysis of the data collected. As outlined in the methodology chapter, the study was divided into a cross sectional point prevalence study and a descriptive non-experimental prospective cohort incidence study.

In this chapter the results of both of these studies are included and the different statistical approaches which were used, such as descriptive and inferential tests, are described. Also, operational definitions for several risk factors and variables are offered in order to provide a clearer picture of the observed variables. Quantitative data analysis was used to identify the measurements of incidence and prevalence as well as to identify risk factors, and measure the predictive validity of the Braden Q and the Glamorgan RASs.

First, a brief description is given of how data were prepared before being analysed using the Statistical Package for Social Sciences (SPSS) version 17.0.

4.2 PRE-ANALYSIS PREPARATION OF THE DATA

Prior to analysis, the data was prepared in a series of steps, which included:

- Clearing the data of errors.

- Re-checking any missing data (personal or system errors).

- Defining variables and giving them proper labels.

- Re-arranging certain variables, either by collapsing categories or changing measurement levels.

- Comparing the SPSS data file with paper copies to ensure accurate data entry.

It was necessary to prepare the data before starting the analysis to be sure that there was no missing data, there were no errors in data entry, no typing errors, or no mistakes made in defining the variables. Missing data were re-checked to clarify the reasons for their being missed, due to personal or system error, using descriptive frequency tables on SPSS.

As already mentioned, all variables were given a clear definition (operational definition), with a precise measurement level and specific calculations. This was important so that each variable would not be mistaken with any other concept and so that information about the way that each variable in this study was calculated and considered was accurately presented.

Moreover, some types of data were rearranged in a manner which would facilitate analysis. This was done, firstly, by collapsing categories of some variables since there were some categorical variables with so many categories or sub-groups that it was difficult to begin the analysis. An example of such a variable was the medical diagnosis of each subject in the study. It was decided that medical diagnosis sub-groups with only a limited number of subjects would be included in one sub-group called "other" and

diagnoses with no subjects identified during the data collection were omitted. The gathering of sub-groups was based on existing literature and previous knowledge of each variable.

Additionally, variables which were measured on a continuous scale had to be changed to categorical measurements both for ease of grouping subjects for comparison, and because some inferential statistics would be difficult to apply to continuous variables. In some cases, continuous variables were made categorical for practical applicability, since there were some variables for which the researcher was not interested in the actual numeric value, but in the clinical meaning of the value.

For example, in the serum albumin test, the researcher was interested only in the tests which showed low albumin values, since low albumin level is linked in previous literature with PU development (Anthony et al., 2011, Willock et al., 2007), but not with normal or high values. Here, the actual numeric value would not be as significant to the results of the research as the classification of children into two groups; one with low albumin levels, and the other with normal values. A suitable label and measurement level for each variable was specified to ensure its clear identity. A precise measurement level was a necessary precursor for a correct next step analysis.

Finally, all data entered were re-checked and compared with the data available on the original data collection papers to minimize the risk of error.

4.2.1 Variable groups and operational definitions

As previously mentioned, each variable was given a specific operational definition, to prevent misinterpretation within variables. There were 46 variables in this study, divided into five groups purely for ease of classification and grouping. These five groups were:

1. Variables that describe ward / patient condition.

2. Biological / laboratory (Lab) test related variables.

3. Variables that describe PUs (no., category, location etc.).

4. Glamorgan RAS' sub-items.

5. Braden Q RAS' sub-items.

These variables were subjected to different statistical tests, both descriptive and inferential. The type of test used depended on the nature of the variable and its relatedness to the observed outcome (whether PU developed or not). Also, some variables were tested based on univariate analyses while others were tested on both univariate and multivariate statistics. This choice depended on many factors, such as level of measurement, level of significance, whether or not they violated multivariate statistics assumptions and others, which will be explained later in this chapter.

- **Group one: Variables which describe ward / patient condition**

This group includes variables which describe patients' condition during ICU/ hospital admission, namely age, gender, medical diagnosis, Glasgow coma scale score (GCS), gestational age, development of any adhesive injury, need for MV, and positive end expiratory pressure (PEEP) level. It also includes variables related to the admission ward (type of ward/speciality), and other variables related to patients' residence in the ward, such as length of stay (LOS), number of follow-up assessments, and the reason for follow-ups being discontinued.

Age was sub-divided into two groups. The first dealt with children aged less than one year, whose ages were entered into SPSS as 'age in days'. The second group included children from 1 to 18 years old, who were labelled according to 'age in years'. This was done to facilitate data entry and analysis where such a wide age range existed, and also in view of the fact that the vast majority of the sample were infants of less than one year of age. Both variables were continuous.

Gender was a dichotomous variable (male/ female). **Medical diagnosis** was entered under 'case classification', a categorical variable which included six sub-categories (Respiratory, Cardiac and Circulatory, Metabolic, Infectious, Neurological, and Other).

'Other' diagnoses included gastric, morphologic and growth problems. The recorded diagnosis was the primary medical diagnosis of patients when admitted to the ICU (incidence study) or hospital (prevalence study). **Gestational Age** was entered both as a continuous variable (weeks in uterus prior to delivery), and categorical (Full Term, if GA ≥ 37 weeks or Preterm, if GA < 37 weeks).

Data related to patients being on **mechanical ventilators** was also gathered. There was one dichotomous variable, describing whether a patient was on an MV at the first assessment (assessment no. = 0) (yes/no). **The level of PEEP** on MV settings was also observed (in this sample measured by H2O level), as was **the duration the patient had spent on the MV in days** (continuous variable). A **GCS** score was also calculated based on the paediatric/ infant GCS criteria which were used in the hospital where the data collection was undertaken. This score ranged from a minimum score of 3 (unconscious) up to a maximum of 15 (fully conscious). This continuous variable was important for measuring the motor, verbal and sensory responses of patients.

The final variable related to **'adhesive injury'**. The decision to collect information on this variable was only taken once the data collection process was underway and it was added because it was seen to be a highly prevalent problem, especially in NICU. It is a dichotomous variable which establishes whether or not a child has sustained a skin injury from plaster stripping or the application of adhesive products.

Other variables in this group were connected to the **admission ward**. In the incidence study, the admission ward was one of 4 ICUs (PICU, GICU, NICU, and GIMU). In the prevalence study, admission wards were grouped into four major categories (medical, surgical, critical units, and newborn). Patients' length of stay (**LOS**) in the ICU was recorded as a continuous variable in days. However, LOS in the prevalence study refers to the patient's entire hospital stay, and not in a particular ward/ unit, up until the day the survey commenced.

The number of observations carried out for each patient during the follow-up period in the incidence study was calculated (as discussed earlier in the methodology chapter, this

could not be less than two and not more than twelve observations, including the initial observation on admission).

The **reason for discontinuing the study** was recorded as a categorical variable as follows: the patient was discharged, died, or the follow-up period (8 weeks) was ended.

- **Group two: Biological/ laboratory test related variables**

This group of variables covers all important factors related to the patient's physiological condition during the relevant ICU admission. They include biological measures such as the vital signs blood pressure (BP) and temperature, and other key indicators of a patient's condition such as acidemia, hypoxemia, and body weight. Also noted were the results of certain laboratory tests which have been shown to be associated with PU development in previous literature. Such diagnostic tests are: serum Potassium level (K), Sodium (Na), Urea and Creatinine, glucose level, C reactive protein (CRP), and Bilirubin level. All these were considered based on Pillitteri (2010).

Blood pressure reading (BP) means the non-invasive arterial blood pressure first reading recorded on the initial assessment (assessment 0) on admission. It is measured in mm Hg and recorded both as systolic and diastolic measures. This variable is continuous.

Body temperature (Temp) refers to the external body temperature taken during the initial assessment (0) on admission. It is a continuous variable measured in degrees Celsius (C˚).

This variable was intended to be omitted from the multivariate analysis when the regression model combined all risk factors with the Glamorgan sub-items. This was in order to reduce the Multicollinearity effect (discussed later) when Temp was combined with Hyperthermia sub-score on the Glamorgan scale.

Acidemia and **Hypoxemia** were measured based on the arterial blood gases (ABGs) readings. This was done by documenting PH, PCO2, PO2, and HCO3 levels. Both of the variables were recorded as dichotomous as the actual values were used to demonstrate simply whether Acidemia/Hypoxemia existed or not (Yes/No). Acidemia

was considered to exist if (PH < 7.35; PCO2 > 45 mmhg or HCO3 < 22). Hypoxemia was considered to occur if PO2 (< 80 mmhg).

Body weight was recorded as a continuous variable in Kilograms (Kgs). This was omitted from the multivariate analysis to reduce duplication with the weight sub-item in the Glamorgan RAS, and the weight changes in nutrition sub-item in the Braden Q RAS. For the multivariate analysis, weight was taken into consideration based on the weight centile charts as recommended by the Glamorgan risk scale. It was classed as a categorical variable, recorded as either below 10^{th} centile or 10^{th} centile and above (Appendix 3.4).

All **laboratory tests** were conducted on blood serum. The results were measured as actual values and entered into the SPSS as continuous variables, except in the case of the CRP value which was a dichotomous (negative/ positive) test. All of these tests were recorded in the initial assessment (0), within 24 hours of admission.

- **Group three: Variables which describe PUs.**

These variables involve descriptions related to the observed outcome (dependent variable DV), which is PU development (Yes/ No). The descriptors include the number of ulcers developed by each patient in the study and the category and location of the most severe ulcers of each patient. Whether the patient had single or multiple ulcers was also noted.

Categorising PUs was based on the EPUAP and NPUAP classification system, as previously mentioned in the methodology chapter. All these variables were dealt with through descriptive analysis, as they only describe the outcome (PU development) and are not considered predictors of the outcome. Therefore, none were analysed by inferential statistics.

- **Group four: Glamorgan RAS sub-items.**

This group contains the Glamorgan RAS sub-items. There are nine sub-items (Appendix 1.10), which were dichotomous variables - except for one ordinal variable (mobility) – and were entered in both univariate and multivariate analyses. All,

however, were dealt with as ordinal variables, since they all originated from a continuous measurement scale (risk scores). A description of each item was provided in the methodology chapter.

- **Group five: Braden Q RAS' sub-items.**

This group contains the Braden Q RAS' sub-items. There are 7 sub-items in total (Appendix 1.11), which were all ordinal variables. They were entered in both univariate and multivariate analyses. A description of each item was included in the methodology chapter.

4.3 STATISTICAL RESULTS

Statistical analysis for this study involved both descriptive and inferential statistics. Descriptive statistics were used for both categorical variables (as frequencies and percentages), and for continuous variables (mean, median, and standard deviation measures). Tables and graphs to show the descriptive nature of the sample will be shown in each relevant section separately.

Inferential statistics were used to answer the research questions, and to test the research hypotheses. Both univariate and multivariate statistics were used. Univariate analysis for this data set included contingency tables (Cross-tabulation) and the *Chi square test* (χ^2). The *Fishers' Exact test* was used in cases where the *Chi square* test assumption was violated.

Contingency tables were used to show the frequencies and percentages of subjects in each category whether they were PU patients or were PU-free. The Chi square test was used to measure any significant difference in the proportion of patients with PU compared to those without PU in regard to the independent variables that had been tested. *Fisher's exact test* replaced the *Chi Square test* in cases where the variables had violated its assumption of frequency; more than 20% of frequencies were less than 5.

For continuous variables with normal distribution, the *parametric independent t-test* was used. Only one variable (serum potassium) was found to be normally distributed.

For the purpose of testing the normality of the continuous variables' distribution, the *one sample Kolmogorov-Smirnov test* was applied. Variables which were not normally distributed and were at least ordinal were tested with the *non-parametric Mann Whitney U test*. These tests were used to identify whether there was a significant difference between patients with PU compared to those who were free of PU, in relation to several independent variables. As is the nature of univariate tests, the association between each variable and the outcome was tested separately.

The next step was to enter all of the variables found to be significant inunivariate analysis into logistic regression models (multivariate). This type of regression was necessary in the current study because of the nature of the observed outcome (binary DV), and the nature of the predictors (a mix of categorical and continuous IVs). Binary logistic regression was used to test the relationship between a group of predictors all at once, and one binary outcome (development of PU or not).

Receiver operating characteristics (*ROC*) was used to measure the predictive validity of the two RASs used: Glamorgan and Braden Q. In this test, the area under the curve (AUC) for both scales was measured and compared, in order to identify which scale was more predictive in distinguishing patients who developed PUs from those who did not. Also, each scale's total score was compared with its sub-items (if at least ordinal) based on their AUC. Categorical data are not suitable for testing with ROC as, unlike ordinal and continuous data, they lack different thresholds which tests can be based on.

A significance level of 0.05 (α- level) was set for all tests used. This cut-off score was based on previous similar PU incidence and risk factors studies of paediatric and adult.

This section will outline the results of the descriptive and inferential statistical testing detailed above. There will be two separate discussions of the prevalence and the incidence studies, because of their distinct samples, different study design, and variant findings.

4.3.1 Study One: Point Prevalence Survey.

- **Descriptive Analysis**

4.3.1.1 Sample Description:

A total of 129 children were inpatients on the day the prevalence study took place. Of these children extracted by the hospital's computerised system lists, 8 were ≥ 18 yrs old, seven patients were admitted to the 'day care' unit and two were in the 'isolation' unit. Four patients refused to participate and their consent was not obtained, and one patient was not available in his room during the examination time. In short, twenty two patients were excluded from the study, yielding a final sample of 107 patients (82.9%). (Table 4.1)

Table 4.1: Children Excluded from the Prevalence Study

Reason for exclusion	Total no. of cases	Percentage (n=129) (%)
Age ≥ 18 yrs old	8	6.2%
Admitted in day care unit	7	5.4%
Admitted in isolation unit	2	1.6%
No consent form	4	3.1%
Patient away from ward (in OR)	1	0.8%

The data was collected in one university–affiliated tertiary care hospital. More than half of the children who participated in the study were male (64.5%, n=69). Their ages ranged from at least one day old (as per the inclusion criteria) and up to, but not yet, 18 years old on the day of the study. The majority of the sample were neonates aged less than one week (28.9%, n=31), and more than half of the children studied were below one year of age (n=62, 57.9%).

Since it was difficult to calculate the median age of the whole sample, where some children were aged in days and others in years, two medians were calculated. For the group who were less than one year old (infants) the median was 43 (IQR= 25) days, while for the second group, who were aged one year and above, the median was 6 (IQR= 10) years.

For the purposes of simplification and clustering, patients were grouped into four major categories or wards: internal medicine, surgery, critical care units, and neonates' wards. The largest two groups (n=31, 29%) were patients in either the surgical wards or the critical care units, followed by the medical wards (n= 24, 22.4%) and newborn ward (n=21, 19.6%) respectively.

Most of the patients in this sample were admitted for less than 3 days (hospital LOS). The median LOS from the admission date until the survey time was 4 (IQR= 7) days. (See Table 4.2)

Table 4.2: Prevalence Study Sample' Characteristics

Demographical data	Sample (n=107) N (%)
Speciality	
Internal medicine wards	24 (22.4%)
Surgery wards	31 (29%)
Critical care units	31 (29%)
Newborn units	21 (19.6%)
Gender	
Male	69 (64.5%)
Female	38 (35.5%)
Age	
Less than 7days	31 (28.9%)
8 days - < 1month	16 (15%)
1mon- < 6mon	8 (7.5%)
6mon- < 1year	7 (6.5%)
1yr- < 3yrs	9 (8.4%)
3yrs- < 6yrs	10 (9.3%)
6yrs- < 12yrs	11 (10.3%)
12yrs- < 18yrs	15 (14%)
Length of stay	
1-3 days	43 (40.2%)
4 days – 1 week	27 (25.2%)
1 week- 2 week	21 (19.6%)
2 week- 3 week	6 (5.6%)
3 week- 1month	7 (6.5%)
1month- 2month	2 (1.8%)
2month- 76 days	1 (0.9%)

4.3.1.2 Prevalence of Pressure Ulcers

a) Rate and Characteristics of PU-patients:

Of the 107 patients assessed, eight had developed a total of 13 PUs (7.5%). If cases of category *I* PUs were excluded, the prevalence rate would be 2.8% (n=3). The point prevalence rate is calculated according to the following equation:

$$\textbf{Prevalence rate} = \frac{\textbf{Number of PU-patients on survey day}}{\textbf{Total number of assessed children}} \times 100\ \%$$

The majority of PU-patients had developed device-related ulcers (75%, n=6) and seven out of the 13 ulcers identified were of this type (53.8%). If these ulcers were excluded, only three patients (37.5%) would be recorded as having ulcers, lowering the prevalence rate to 2.8% (n=3), taking into consideration that one child had developed both types of ulcers. Table 4.3 shows the different categories with the number of each identified ulcer, according to the EPUAP classification system (EPUAP and NPUAP, 2009).

Table 4.3: Total Number and Classification of PU According to its Source

	Total no. of ulcers	Category I	Category II	Category III	Category IV
Surface-related PU	6	2	1	3	0
Device- related PU	7	6	1	0	0

Almost all PU-patients were admitted to ICUs (n=7, 87.5%), except for one child who was a patient in the surgical ward (n=1, 12.5%). No PU cases were found in the medical and newborn units. According to the results of the *Chi Square* χ^2 test, there was a significant difference between PU prevalence in each of the wards ($\chi^2=14.7$, $d.f= 3$, $P=0.002$).

There was variation in the number of ulcers found for each child. Fifty percent of all children with PUs (n=4) had only one ulcer, three patients had two ulcers (37.5%), and one patient had three ulcers (12.5%).

The sites most affected with PUs were the face (38.5%, n= 5), followed by the occiput and 'neck & shoulders', each with the same number of affected children (15.3%, n=2).

However, the most severe PUs (category *III*) were located with even frequency in the sacrum, occiput and ankle (one PU in each site, 7.7%). Most observed ulcers were of partial thickness category *I* and *II* (n=10, 77%). Two patients developed three category *III* ulcers (23%), but no patients in this sample had category *IV* ulcers. As seen in (table 4.3) above, all device-related ulcers were superficial, while all the category *III* ulcers were surface-related. (See Figure 4.1 for PUs locations and categories)

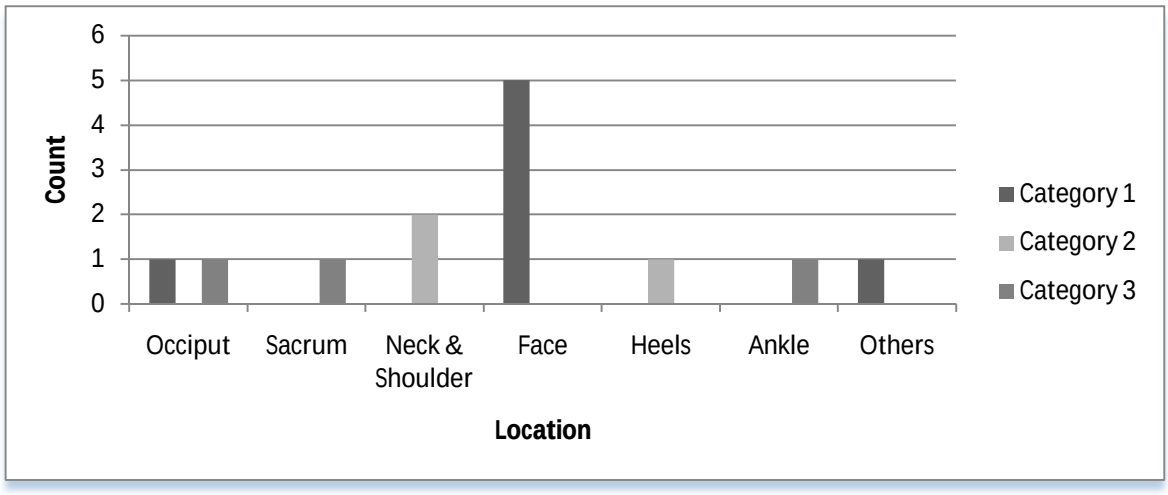

Figure 4.1: Locations and Categories of Ulcers/ Prevalence study

Despite the fact that most children in the sample were male, females were most affected by ulcers (n=5, 62.5%). However, continuity correction statistics showed no statistically significant difference between the gender of the patients and the status of having an ulcer or not (*Continuity Correction=1.6, d.f=1, P=0.203*). However, the sample here was too small to reliably infer a statistical relationship between gender and PU formation.

The median LOS from admission until survey time for patients without PU was 4 days (IQR= 7), while in the PU group the median was 11.5 days (IQR= 27). There was a significant difference between the LOS for the two groups as shown by the *Mann-Whitney U test* results (*U=174.5, p=0.008*). Also, PUs were most prevalent in the children younger than one year old (n= 5, 62.5%). For more details about the characteristics of PU-patients, see (Table 4.4).

Table 4.4: The Characteristics of PU-patients in the Prevalence Study Sample

PU-patients	(N=8)
Prevalence *	
Including category *I*	8 (7.5%)
Excluding category *I*	3 (2.8%)
Prevalence according to ward	
Internal medicine	0 (0%)
Surgery wards	1 (12.5%)
Critical care units	7 (87.5%)
Newborn unit	0 (0%)
Location of PUs **	
Sacrum	1 (7.7%)
Neck & Shoulder	2 (15.3%)
Occiput	2 (15.3%)
Face	5 (38.4%)
Heels	1 (7.7%)
Ankle	1 (7.7%)
Other areas (Head)	1 (7.7%)
Category of PUs**	
Category I	8 (62%)
Category II	2 (15%)
Category III	3 (23%)
Category IV	0 (0%)
Number of ulcers for each patient	
Single ulcer (1)	4 (50%)
Multiple ulcers (2)	3 (37.5%)
Multiple ulcers (3)	1 (12.5%)
Age of PU-patients	
< 1year	5 (62.5%)
≥ 1 year	3 (37.5%)
Gender of PU-patients	
Male	3 (37.5%)
Female	5 (62.5%)
ICU Prevalence rate (n= 31)	7 (23%)
Prevalence rate in under one year old patients (n=62)	5 (8.1%)

***** Prevalence rate based on the total sample (n= 107)
****** Most affected sites based on the total number of ulcers rather than the total number of subjects in the sample (n= 13).

4.3.2 Study Two: Incidence and Risk Factors Survey

- **Descriptive analysis**

4.3.2.1 Sample Description

The sample consisted of a total of 212 patients. These were newly admitted children (within 24 hours of admission) who were recruited from three ICUs for paediatrics; the neonatal intensive care unit (NICU), paediatric intensive care unit (PICU), and general intermediate care units (GIMU). These units were chosen because all critically ill children aged from birth to 18 years old would be admitted to one of these units.

Another unit which was within the scope of this study was the general intensive care unit (GICU) to which children aged between 14 to 18 years can be admitted. However no potential subjects were admitted to this unit during the five month period of data collection.

The initial number of subjects was 281, but 69 of them did not meet the inclusion criteria. Forty two patients (60.9 %) had less than two assessments during the study period (i.e. only the initial assessment and no follow-ups), nineteen had no consent forms completed (27.5%), and one patient was over 18 years old on the day the study was carried out (1.4%). In addition, four children were admitted to isolation rooms (5.8%), one was difficult to reposition for assessment (due to deteriorated health condition) (1.4%) and two patients were shown to have existing PUs at initial assessment (2.9%). (See Table 4.5)

Table 4.5: Excluded Patients' Characteristics in the incidence Survey

Reason for exclusion	Total no. of cases	Percentage (n=69) (%)
Age ≥ 18 years old	1	1.4 %
Less than 2 consecutive assessments	42	60.9 %
In isolation unit	4	5.8 %
No consent form	19	27.3%
Difficulty in positioning	1	1.4 %
Existing PU on first assessment	2	2.9 %

The remaining 212 patients were aged from birth up to 17 years old. Most of these were newborn (79.7 %, n= 168), ninety-seven of whom were born preterm (37%).The lowest

number of subjects were preschoolers (age 3 – 5 years old) (0.9%, n= 2). More than half of the subjects (58.5%) were male and 41.5% female. The vast majority of the sample were cared for in NICU (79.7%, n= 168), followed by PICU (19.8%, n= 42), and GIMU (0.5%, n= 1).

The most common medical diagnosis of the total sample was respiratory disorders (59.9%) followed by metabolic and infectious diseases respectively (11.8%; 10.8%). The LOS ranged from 3 to 56 days, with the *Median (IQR) = 5 (5)*. The stays ended by discharge (n= 202, 95.3%), patient death (n=9, 4.2%), or because the end of the maximum follow-up time - 12 assessments over 2 months (n=1, 0.5%) - was reached. (See Table 4.6)

Table 4.6: Demographical Characteristics of the Incidence Study Sample (n=212)

Characteristics	Total sample N (%)
Number of subjects	212
Age (min-max)	0 days – 17 years
- Newborn (0-30 days)	168 (79.2%)
- Infant (31 days-1 year)	21 (9.9%)
- Toddler (>1-3years)	10 (4.7%)
- Preschool (>3-5)	2 (0.9%)
- School (>5-12 years)	7 (3.3%)
- Adolescent (>12-18years)	4 (1.9%)
- Missing data	0 (0%)
Gender	
- Male	124 (58.5%)
- Female	88 (41.5%)
- Missing data	0 (0%)
Specialty	
- PICU (Paediatric ICU)	42 (19.8%)
- NICU (Neonatal ICU)	169 (79.7%)
- GIMU (General intermediate unit)	1 (0.5%)
- GICU (General ICU)	0 (0%)
- Missing data	0 (0%)
Patient's case classifications	
- Respiratory diseases	127 (59.9%)
- Cardiac & circulatory	6 (2.8%)
- Metabolic disorders	25 (11.8%)
- Infectious diseases	23 (10.8%)
- Neurological conditions	13 (6.1%)
- Others (gastric, morphologic, growth retardation, etc)	18 (8.5%)
- Missing data	0 (0%)
Gestational Age	
- Pre-term (<37 gestational weeks)	79 (37.3%)
- Full-term (≥37 gestational weeks)	97 (45.8%)
- Missing data	36 (17%)
Adhesive Injury	
- Yes	39 (18.4%)
- No	173 (81.6%)
- Missing data	0 (0%)
Length of stay	
- Range	3-56 days
- Mean	7.96 days
- SD	8.67
- Median (IQR)	5 (5)
Reasons for stopping study	
- Discharged	202 (95.3%)
- Died	9 (4.2%)
- End of study period (8 weeks)	1 (0.5%)

Each subject included in the study was required to have at least two consecutive assessments (ICU LOS at least 3 days) including assessment 0 (the initial assessment), which would need to be carried out on admission. This was to ensure that each subject was free of PU on admission, and to complete the Braden Q and the Glamorgan risk scales so that risk could be measured throughout the follow-up period. The number of assessments carried out on each patient ranged between 2 and 12, with a median of two assessments. (Table 4.7)

Table 4.7: Number of assessments in Incidence Study

Number of assessments	Frequencies N (%)
2	134 **(63.2%)**
3	26 (12.3%)
4	15 (7.1%)
5	11 (5.2%)
6	8 (3.8%)
7	10 (4.7%)
9	3 (1.4)
10	2 (0.9%)
11	2 (0.9%)
12	1 (0.5%)
Range: 2-12 assessments, *Median= 2*	

4.3.2.2 Incidence and Characteristics of PU-patients

Of the 212 patients who were PU-free on initial assessment, 19 developed a total of 29 ulcers throughout the follow-up period (8 weeks). The incidence rate was 9%, or as low as 5.2% when category *I* PUs were excluded. Most patients had device-related ulcers (63%, n= 12). Around 79% of the PUs identified affected children admitted to the NICU (n= 15).

$$\textit{Incidence rate} = \frac{\textit{No. of patients who developed PU during follow-up period}}{\textit{Total no. of assessed children during follow-up period}} \textit{ X 100\%}$$

The location of most observed ulcers were in 'chest and shoulder' (20.7%, n=6). The next most problematic sites were areas labelled 'other', a category which included arms, ears, back and buttocks (17.2%, n= 5). Came on next, 'ankle and feet', mouth, and nose (incidence for each 13.8%, n= 4). Category *II* PUs were the most frequently occurring (48.3%, n= 14), followed by category *I (41.4%, n= 12), and* then category *III* (10.3%, n=3) (See Figure 4.2). Yet, the most severe ulcers (category *III)* in the study as a whole were found on the occiput (two out of three), and heels (one ulcer). None were classified as category *IV*. Most PU-patients had single ulcers (63.2%, n= 12) compared to the seven others who had two or more ulcers (36.8 %). (See table 4.8 & 4.9)

Table 4.8: Pressure Ulcer Incidence Rate (N= 212)

Incidence	**Total sample N (%)**
Developed PU (Incidence)	
- Yes	19 (9%)
- No	193 (91%)
Incidence	
- Including category *I*	19 (9%)
- Excluding category *I*	11 (5.2%)

Table 4.9: Characteristics of PU-patients in Incidence Study

Characteristics	**% (n=19)**
Incidence	
- Pressure related ulcers	7 (36.8%)

- Device related ulcers	12 (63.2%)
Incidence according to ward	
- PICU	4 (21.1%)
- NICU	15 (78.9%)
- GIMU	0 (0%)
Location of ulcers*	
- Occipital	3(10.3%)
- Heel	3(10.3%)
- Ankle and feet	4(13.8%)
- Chest and shoulder	6(20.7%)
- Nose	4(13.8%)
- mouth	4(13.8%)
Others (arms, back & Buttocks, ears)	5(17.2%)
Category of ulcers*	
- Category *I*	12 (41.4%)
- Category *II*	14 (48.3%)
- Category *III*	3 (10.3%)
- Category *IV*	0 (0%)
Number of ulcers	
- Single	12 (63.2%)
- Two ulcers	4 (21.1%)
- Three ulcers	3 (15.7%)

* Percentages are based on the total number of ulcers (n= 29 ulcers in 19 patients)

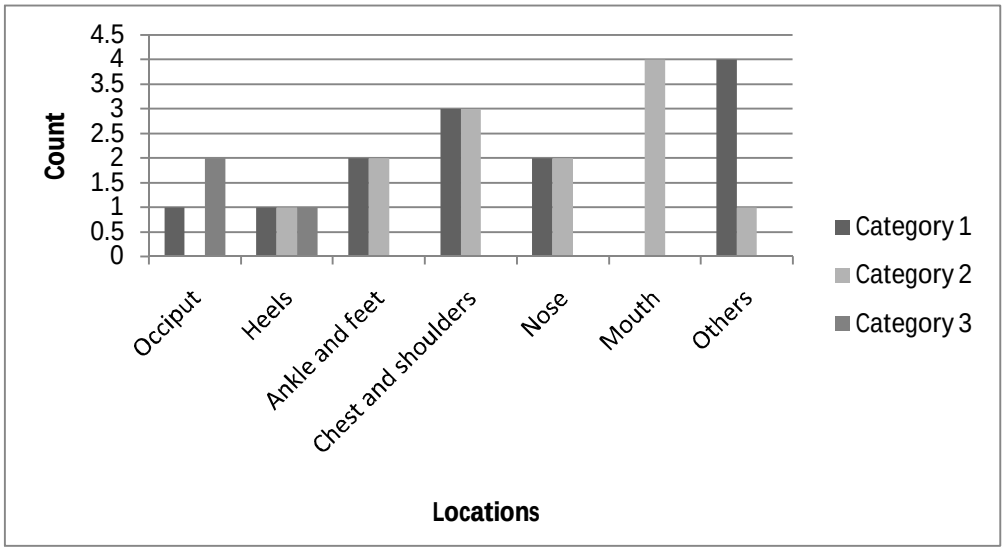

Figure 4.2: Location and Categories of Ulcers

The table below (Table 4.10) shows the categories of PU according to the EPUAP and NPUAP classification system, and whether the pressure ulcers were device-related or surface-related.

Table 4.10: Total Number and Classification of PU According to its Source

	Total no. of ulcers	Category *I*	Category *II*	Category *III*	Category *IV*
Surface-related PU	9	4	2	3	0
Device- related PU	20	8	12	0	0

4.3.2.3 Results of the univariate analysis

For simplification, all variables entered into the univariate analysis test were classified into two groups: categorical variables and continuous (numerical) variables.

Use of the *Chi Square (χ^2)* test and *Fisher's Exact* test for categorical variables, and the *Mann Whitney U* test and *independent samples t- test* for continuous variables, revealed seventeen variables to be significantly related to PU development in this population, where the significance level was $\alpha \leq 0.05$ (See Table 4.11 & 4.12).

Table 4.11: The Results of Univariate Analysis for Categorical Risk Factors

Variable	N	*d. f*	X^2/*Fisher's*	*P* value	Test used
Age groups	212	5	7.83	0.106	Fisher's
Gender	212	1	0.62	0.431	Chi-square
Case classifications	212	5	4.23	0.451	Fisher's
Gestational age groups	176	1	0.92	0.338	Chi-square
BP classifications	199	1	2.95	0.114	Fisher's
Na classifications	157	2	1.63	0.387	Fisher's
K classifications	156	2	0.57	0.883	Fisher's
Urea classifications	157	2	2.06	0.356	Fisher's
Creatinine classifications	157	2	1.97	0.471	Fisher's
Bilirubin classifications	176	2	2.13	0.345	Chi-square
Glucose classifications	166	2	1.41	0.524	Fisher's
CRP classifications	183	1	1.78	0.369	Fisher's

GCS classifications*	212	2	22.68	**<0.001**	Chi-square
Being on MV*	212	1	20.4	**<0.001**	Chi-square
Skin condition	212	2	4.32	0.080	Fisher's
Presence of Infection	212	1	0.055	0.815	Chi-square
Presence of academia	196	1	2.36	**0.124**	Chi-square
Presence of hypoxemia	191	1	0.01	0.921	Chi-square
Equipment / Glamorgan*	212	1	11.94	**0.001**	Chi-square
Anemia/ Glamorgan	212	1	1.15	0.604	Fisher's
Pyrexia/ Glamorgan	212	1	0.401	1.00	Fisher's
Poor perfusion/ Glamorgan	212	1	1.36	0.612	Fisher's
Nutrition/ Glamorgan*	212	1	4.28	**0.038**	Chi-square
Albumin/ Glamorgan	212	1	0.104	1.00	Fisher's
Weight/ Glamorgan	212	1	1.54	**0.215**	Chi-square
Incontinence/ Glamorgan	212	1	3.38	0.098	Fisher's
Glamorgan risk classification*	212	3	19.73	<0.001	Fisher's
Braden Q risk classifications*	212	1	10.51	0.003	Fisher's

*** Significant at α≤ 0.05 in the univariate analysis**
Shaded variables: violate *Chi Square χ^2 test* assumptions.

Table 4.12: The Results of Univariate Analysis for Continuous Risk Factors

Variable	N	Test used	*P* value	Mann-Whitney U/ t-test	Z score
Mobility/ Glamorgan*	212	MW test	**<0.001**	1125	-3.428
Mobility / Braden Q*	212	MW test	**<0.001**	1098	- 3.512
Nutrition / Braden Q	212	MW test	0.265	1572	-1.115
Tissue perfusion/ Braden Q*	212	MW test	**0.01**	1246.5	-2.531
Sensory perception/ Braden Q*	212	MW test	**<0.001**	808.5	-4.270
Moisture/ Braden Q*	212	MW test	**<0.001**	829.5	-4.649
Friction and shear/ Braden Q*	212	MW test	**<0.001**	927.5	-3.657
Activity/ Braden Q*	212	MW test	**<0.001**	785	-4.471
Age in years	24	MW test	0.559	32.5	-0.584
Age in days*	188	MW test	**<0.001**	595	-3.527
LOS*	212	MW test	**<0.001**	437	-5.570
Systolic BP	199	MW test	0.272	1448	-1.098
Diastolic BP	199	MW test	0.683	1612.5	-0.409
Mean BP	199	MW test	0.546	1566	-0.603
Serum Na	157	MW test	0.274	1108.5	-1.093
Serum K	156	t-test	**0.186**	1.328	d.f=154
Serum urea	157	MW test	0.499	1185.5	-0.676
Serum Creatinine	157	MW test	0.679	1234	-0.414
Serum Bilirubin	176	MW test	0.482	1211	-0.704
Serum glucose	168	MW test	0.881	1120.5	-0.150
GCS score*	212	MW test	**<0.001**	712.5	-4.611
Duration on MV in days*	82	MW test	**<0.001**	225	-3.767
PEEP level*	78	MW test	**0.047**	361.5	-1.989

*** Significant at α≤0.05 in univariate analysis**

Of these variables, five were categorical, seven ordinal, and five continuous (Table 4.13). All the significant variables would be entered to the *LR* model (multivariate analysis) as a next step, except for those which violated the *Chi square* (χ^2) test assumptions (frequency not less than 5 in at least 80% of the contingency table cells), which is the same as the logistic regression goodness of fit assumption of low frequencies (Field, 2009).

Table 4.13: Significant Risk Factors by Univariate Analysis (P≤0.05)

Variable	Type	*P* value
Being on MV	Categorical	**<0.001**
Equipment/ Glamorgan	Categorical	**0.001**
Nutrition/ Glamorgan	Categorical	**0.038**
Glamorgan risk classification	Categorical	**<0.001**
Braden Q risk classifications	Categorical	**0.003**
Duration on MV	Continuous	**<0.001**
Age in days	Continuous	**<0.001**
LOS	Continuous	**<0.001**
GCS score	Continuous	**<0.001**
PEEP level	Continuous	**0.047**
Mobility/ Glamorgan	Ordinal	**0.003**
Sensory perception/ Braden Q	Ordinal	**<0.001**
Mobility / Braden Q	Ordinal	**<0.001**
Tissue perfusion/ Braden Q	Ordinal	**0.01**
Moisture/ Braden Q	Ordinal	**<0.001**
Friction and shear/ Braden Q	Ordinal	**<0.001**
Activity/ Braden Q	Ordinal	**<0.001**

According to the findings of univariate analysis, only three sub-items of the Glamorgan RAS were significant, in addition to the total Glamorgan risk classifications (no risk, risk, high risk, and very high risk). On the other hand only one sub-item of the Braden Q RAS – *Nutrition* - failed to prove significant. (Table 4.14)

Table 4.14: Glamorgan' and Braden Q' Significant Sub-items by Univariate Analysis

Sub-item	Glamorgan	Braden Q	*P* value (≤0.05)	
			Glamorgan	Braden Q
Mobility	**X**	**X**	**<0.001**	**<0.001**
Activity		**X**		**<0.001**
Equipment	**X**		**0.001**	
Nutrition	**X**		**0.038**	
Sensory perception		**X**		**<0.001**
Tissue perfusion		**X**		**0.01**
Friction and shear		**X**		**<0.001**
Moisture		**X**		**<0.001**
Risk classifications	**X**	**X**	**<0.001**	**0.003**

a) Comparing PU and PU-free groups

While comparing children who developed PUs with those who did not, it was noticed that the former group had a lower consciousness score (median= 11 vs. 14 GCS). Also, these children spent more time on mechanical ventilators than the non-PU patients (n= 19, 89.5 % vs. n= 193, 33.7%).

By comparing GCS with the sensory perception score on the Braden Q RAS, it was found that all children with PU had suffered from sensory limitations in different degrees, with the highest number of ulcer sufferers with slightly limited (n=8, 42.1%) and very limited sub-scales (n=7, 36.8%). The Braden Q sensory perception sub-item and GCS were both shown by the *Mann-Whitney U* test to be highly significantly associated with PU development (P< 0.001).

According to the Glamorgan RAS, the vast majority of children with PU had limited mobility (n=12, 63%), poorer nutritional condition (n=18, 94.7%), and all were supported by medical equipment. In contrast, PU-free patients were more mobile (n=53, 27.5%). However, *nutritional problems* and the *existence of equipment pressing on*

patients' skin were also observed in the case of more than half of the PU-free patients (69.4%, 56.5% respectively). (Table 4.15)

Table 4.15: Descriptive for Significant Categorical Risk Factors based on Univariate Analysis

Risk factors	PU Group		PU-free Group	
	Frequency (%)	**N**	**Frequency (%)**	**N**
GCS classification		19		193
- **Full conscious (13-15)**	2 (10.5%)		127 (65.8%)	
- **Semi conscious (9-12)**	13 (68.4%)		54 (28%)	
- **Unconscious (3-8)**	4 (21.1%)		12 (6.2%)	
Being on MV		19		193
- **Yes**	17 (89.5%)		65 (33.7%)	
- **No**	2 (10.5%)		128 (66.3%)	
Duration on MV:		17		65
- **Four days and More**	14 (73.7%)		24 (36.9%)	
- **Less than 4 days**	3 (15.8%)		41 (63.1%)	
Braden Q risk classifications		19		193
- **At risk**	9 (47.4%)		32 (16.6%)	
- **No risk**	10 (52.6%)		161 (83.4%)	
Equipment/ Glamorgan		19		193
- **Presence of pressing equip**	19 (100%)		109 (56.5%)	
- **Absence of pressing equip**	0 (0%)		84 (43.5%)	
Inadequate nutrition/ Glamorgan		19		193
- **Yes**	18 (94.7%)		134 (69.4%)	
- **No**	1 (5.3%)		59 (30.6%)	
Glamorgan risk classification		19		193
- **Very high risk**	12 (63.2%)		42 (21.8%)	
- **High risk**	7 (36.8%)		69 (35.8%)	
- **At risk**	0 (0%)		8 (4.1%)	
- **No risk**	0 (0%)		74 (38.3%)	

Patients with pressure ulcers, according to the Braden Q sub-items, had moist skin (incontinence, urine and faeces, sweating, drainage, etc) in more than 84% of cases (n= 16) compared with in only 31% (n= 61) of PU-free cases. Also, the vast majority of PU-patients had complained of some degree of *friction and shears* forces (n= 18, 94.7%), limited *activity* (n= 19, 100%), and diminished indicators of *tissue perfusion and oxygenation* measures (n= 17, 89.4%). On the other hand, using both scales, *mobility*

was limited in 12 PU-patients (63.1%) compared to 7 PU-patients with normal mobility (36.9%).

The performance of both Braden Q and Glamorgan RASs was investigated. The former scale was able to classify around half of the PU-patients of being at risk, while the later one gave 100% correct classifications of at-risk patients who in actual fact developed PUs later in the study. However, the Glamorgan scale also mistakenly classified around 62% of PU-free patients to be at risk at the beginning of the study (n= 119) (Table 4.16).

Table 4.16: Descriptive for the Significant Ordinal Risk Factors based on Univariate Analysis

Risk factors	**PU Group**		**PU-free Group**	
	Frequency (%)	**N**	**Frequency (%)**	**N**
Sensory perception/ Braden Q		19		193
- **Completely limited**	4 (21.1%)		11 (5.7%)	
- **Very limited**	7 (36.8%)		29 (15%)	
- **Slightly limited**	8 (42.1%)		72 (37.3%)	
- **No limitation**	0 (0%)		81 (42%)	
Moisture/ Braden Q		19		193
- **Constantly moist**	1 (5.3%)		0 (0%)	
- **Very moist**	3 (15.8%)		11 (5.7%)	
- **Occasionally moist**	12 (63.2%)		50 (25.9%)	
- **Rarely moist**	3 (15.8%)		132 (68.4%)	
Friction and shear/ Braden Q		19		193
- **Significant problem**	1 (5.3%)		4 (2.1%)	
- **Problem**	6 (31.6%)		24 (12.4%)	
- **Potential problem**	11 (57.9%)		76 (39.4%)	
- **No problem**	1 (5.3%)		89 (46.1%)	
Mobility/ Braden Q		19		193
- Completely immobile	4 (21%)		11 (5.7%)	
- Very limited	8 (42.1%)		30 (15.5%)	
- Slightly limited	0 (0%)		14 (7.3%)	
- No limitations	7 (36.9%)		138 (71.5%)	
Tissue perfusion/ Braden Q		19		193
- Extremely compromised	2 (10.5%)		8 (4.1%)	
- Compromised	13 (68.4%)		93 (48.2%)	
- Adequate	2 (10.5%)		17 (8.8%)	
- Excellent	2 (10.5%)		75 (38.9%)	
Activity/ Braden Q		19		193
- **Bed fast**	6 (31.6%)		29 (15%)	
- **Chair fast**	10 (52.6%)		37 (19.2%)	
- **Walks occasionally**	3 (15.8%)		17 (8.8%)	
- **Patient too young to walk**	0 (0%)		110 (57%)	
Mobility/ Glamorgan		19		193

- Great difficulty	4 (21%)		9 (4.7%)	
- Needs assistance	1 (5.3%)		5 (2.6%)	
- Reduced for age	7 (36.9%)		39 (20.2%)	
- Normal mobility	7 (36.9%)		140 (72.5%)	

Around 74 % of children with PUs had been on MV for periods equal to or longer than 4 days, compared with 37% of the PU-free patients. The 'duration on mechanical ventilation' variable was also tested with its actual numeric value, which also demonstrated that PU-patients had spent significantly longer periods on MV than the PU-free patients (Median= 8(6); M= 9.6± 6.1; 95% CI 6.4-12.7).

Patients with pressure ulcers had lengthier ICU stays compared with PU-free patients (Median 13 vs. 5). In addition to the finding that PU-patients spent longer periods on MV than the PU-free group, it was found that they also had a lower average of PEEP setting (Median 5 vs. 9.7) (Table 4.17).

Table 4.17: Descriptive for the Significant Continuous Risk Factors based on Univariate Analysis

Risk factors	**PU Group**				**PU-free Group**			
	n	**Median (IQR)**	**Mean ±SD**	**95% CI**	**n**	**Median (IQR)**	**Mean ±SD**	**95% CI**
Age in days	15	13 (9)	17.7± 15.4	(9.1-26.2)	173	6 (8)	18± 40.2	(11.9-24)
LOS	19	13 (13)	19.5± 15.3	(11.7-27.3)	193	5 (5)	11.2± 10.7	(8.4-13.9)
GCS score	19	11 (1)	9.5± 3.8	(7.6-11.5)	193	14 (3)	10.9± 3.3	(10-11.7)
Duration on MV	17	8 (6)	9.6± 6.1	(6.4-12.7	65	4(4)	5.3± 5.9	(3.8-6.9)
PEEP	17	5 (5.5)	6.2± 2.5	(4.9-7.5)	61	9.7 (5)	7.5± 2.6	(6.8-8.1)

4.3.2.4 Results of Multivariate Analysis

Binary *LR* was used to study the relationship between the set of risk factors (predictors) and the observed outcome (PU development) in the critically ill patients. This type of *LR* was the appropriate analysis to study the effect of all predictors independently on the dichotomous binary outcome. The predictors can be categorical, continuous, or a mix of both.

In this study, the binary outcome was whether PU had developed or not (DV), while the independent variables (IVs) were a mix of categorical and continuous variables.

a) Logistic regression assumptions

To ensure the data entered fit well within the developed model, the following assumptions of *LR* were checked (Field, 2009):

1- Linearity: usually in regression there is an assumed linear relationship between the predictors and the outcome. However, in *LR* the outcome is categorical so this assumption is violated. For this reason, we test for linearity between the logit of the binary outcome and the continuous predictors. In this study, linearity was tested for all continuous variables (which were entered to the model). This was achieved by testing the significance of the interaction term between the predictor and its log transformation (Hosmer and Lemeshow, 2004).

   Only one continuous variable violated this assumption: the 'duration the patients had spent on MV in days'. As shown in (table 4.18), this variable is the only one with a significance level less than 0.05 (*P= 0.017*), which indicates a significant violation of linearity. Consequently, this variable was converted into a dichotomous form (duration < 4days, or ≥ 4days). The cut-off value was derived from previous related literature, as well as from the value of the Median for the length of time spent on MV for the whole sample (*Median= 4 (IQR= 4)*).

Table 4.18: Testing for Linearity

Variables	B	S.E.	Wald	*d.f*	Sig.	Exp(B)
Age in days	.970	21.012	.002	1	.963	2.637
ICULOS	-1.646	21.007	.006	1	.938	.193
K	-2.412	12.209	.039	1	.843	.090
GCS	-.050	6.933	.000	1	.994	.951

PEEP	-5.105	11.908	.184	1	.668	.006
Duration of MV continuous*	1.784	.708	6.342	1	**.012**	5.954
Age in days by lnageindays	-.392	5.607	.005	1	.944	.676
ICULOS by lnLOS	.551	5.605	.010	1	.922	1.736
K by LnK	.883	4.697	.035	1	.851	2.419
GCS by lnGCS	-.220	2.071	.011	1	.916	.803
LnPEEP by PEEP	1.768	4.023	.193	1	.660	5.860
Duration of MV continuous by LnDurationMV *	-.477	.199	5.730	1	**.017**	.620
* Duration of MV variable has a significant linearity problem (P= 0.017)						

1- Multicollinearity: This test assumes that the predictor variables are not highly correlated with each other. Tolerance test less than 0.1, and VIF (Variance Inflation Factor) test more than 10 indicate a multicollinearity problem. In this study, no multicollinearity problems were identified for the set of predictors involved. However, to avoid this problem while testing the sub-items of both the Glamorgan and Braden Q scales, each scale's sub-items were tested separately using different *LR* models (See Table 4.19 & 4.20). This will be discussed later on this section.

Table 4.19: Testing for Multicollinearity/ Significant Glamorgan Sub-items with General Risk Factors

Variables	**Collinearity Statistics**	
	Tolerance	**VIF**
Age in days	.446	2.614
LOS in days	.246	1.964
GCS score	.250	5.618
PEEP level	.747	1.339
Duration (in categories) for being on MV	.238	4.203
Mobility	.364	2.750
Equipment pressing on skin	.885	1.130
Inadequate nutrition	.957	1.045

Table 4.20: Testing for Multicollinearity/ Significant Braden Q sub-items with General Risk Factors

Model	Collinearity Statistics	
	Tolerance	VIF
Age in days	.369	2.711
LOS in days	.192	5.215
GCS score	.177	5.657
PEEP level	.618	1.618
Duration (in days) of being on MV	.223	4.481
Mobility Braden Q	.388	2.578
Activity level	.454	2.204
Sensory perception level	.334	2.994
Skin moisture	.503	1.986
Friction and shear	.395	2.530
Tissue perfusion and oxygenation	.788	1.270

2- Independence of errors: This means that each patient (case) should not be related to others. Therefore, it is not possible to enter several measures or readings for the same patient at several points in time in the same model, since cases should be independent. In this study, the aim was to test each subject independently and only once so no violation of this assumption was committed.

According to Field (2009) there is a further problem for *LR*: having variables with low frequencies. *LR* assumes each variable to have a frequency of not less than one for all cases, and not less than 5 in at least 20% of all variables tested. This is very similar to the assumption of frequency in the *Chi Square* (χ^2) test and, as a consequence, the assumption was tested earlier for the variables in this study while doing the univariate analysis. All variables that violated this assumption were ignored in the multivariate regression analysis (see Table 4.11).

b) Logistic Models

For the purpose of identifying predictors/ risk factors which were significantly related to the occurrence of the observed outcome (PU development), four logistic models were created, and the models were:

1- Model one: Braden Q Scale' sub-items.

2- Model two: Glamorgan Scale' sub-items.

3- Model three: General predictors and Braden Q' sub-items.

4- Model four: General predictors and Glamorgan' sub-items.

These four models were designed to fit the data without violating the assumptions of *LR*. Models one and two were designed to avoid the redundancy of predictors and to prevent the multicollinearity problems since both scales have similar sub-items, such as mobility, nutrition, moisture/ incontinence and tissue perfusion. Also, the models were applied separately for the purpose of comparing the two scales in regard to the significance of their sub-items.

In model one, using the default *entry* method and a cut-off score of 0.05, all predictors which were shown to be significant in the univariate analysis were entered to the model (i.e. all except for 'nutrition'). All six Braden Q sub-items entered failed to prove significant in the multivariate analysis. However, the whole model was able to correctly classify 91.5 % of PU cases, showing significant difference than the constant model (the null hypothesis), χ^2 (6, N= 212) = 24.53, P <0.001. (See Table 4.21)

Table 4.21: Model One/ Braden Q sub-items

Variables	B	S.E.	Wald	*d.f*	Sig.	Exp(B)	95% *C.I* for EXP(B)	
							Lower	Upper
Tissue perfusion	-.069	.361	.036	1	**.849**	.934	.460	1.896
Friction & Shear	-.114	.479	.057	1	**.812**	.892	.349	2.279
Moisture	-.776	.469	2.738	1	**.098**	.460	.184	1.154
Sensory perception	-.606	.470	1.661	1	**.197**	.546	.217	1.371
Activity	-.460	.381	1.459	1	**.227**	.631	.299	1.332
Mobility	.371	.400	.857	1	**.355**	1.449	.661	3.175

In model two, all significant sub-items of the Glamorgan scale (as shown in the univariate analysis) were entered using the same default *Entry* method and using a cut-off score of 0.05. Three sub-items were entered (*mobility, nutrition, and equipment pressing on patient's skin*) but only the *mobility* sub-item showed significance (*OR*= 1.07*, P= 0.037; 95% CI, 1.004-1.149*). (See Table 4.22)

Table 4.22: Model Two/ Glamorgan sub-items

Variables	B	S.E.	Wald	*d.f*	Sig.	Exp(B)	95% *C.I* for EXP(B)	
							Lower	Upper
Inadequate nutrition G6	-.191	1.127	.029	1	**.865**	.826	.091	7.515
Equipments pressing G2	1.279	292.673	.000	1	**.997**	3.593	.000	4.774
Mobility G1	.072	.034	4.366	1	**.037** *	1.074	1.004	1.149

For both scales, Glamorgan and Braden Q, all sub-items, and not only the variables that were shown to have a significant correlation with PU development in the univariate analysis, were entered into two different models. This was done to be sure that none of the non-significant sub-items would show an interesting relation with the PU development in the presence of other sub-items. However, the results were the same as when only the significant sub-items of each scale were used (See Appendices 4.1-4.4).

All Braden Q sub-items that had been entered to 'model one' were entered into 'model three', in combination with other general risk factors. These risk factors had been previously shown to be significantly related to PU development in ICU patients in the univariate analysis, and did not violate the frequency assumption as well. The factors were: 'age in days', 'ICU LOS', 'GCS score', 'whether or not on MV', 'duration ≥ or< 4 days on MV', and 'PEEP level'. The overall model had no significant predictors, since the χ^2 for the whole model showed no significant difference between PU-patients and PU-free patients regarding these predictors; χ^2 *(12, N= 70) = 17.10, P= 0.105*. The full model explained between 21.7% (Cox and Snell R square) and 34.3% (Nagelkerke R square) of the variance in PU status, and correctly classified 80% of cases. (See Table 4.23).

Table 4.23: Model Three/ Braden Q sub-items and General risk factors

Variables	B	S.E.	Wald	Df	Sig.	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
Age in days	-.420	.503	.697	1	**.404**	.657	.245	1.761
ICULOS	.439	.508	.745	1	**.388**	1.550	.573	4.198
GCS	-.545	.445	1.500	1	**.221**	.580	.242	1.387
PEEP	.130	.176	.552	1	**.457**	1.139	.808	1.607
Duration on MV	1.818	1.000	3.304	1	**.069**	6.160	.867	43.74
Mobility	.128	.464	.076	1	**.783**	1.137	.458	2.822
Activity	-.166	.690	.058	1	**.810**	.847	.219	3.275
Sensory perception	.201	.853	.056	1	**.814**	1.223	.230	6.510
Moisture	-.857	.953	.807	1	**.369**	.425	.066	2.750
Friction and shear	.462	1.095	.178	1	**.673**	1.588	.186	13.589
Tissue perfusion	.291	.610	.228	1	**.633**	1.338	.405	4.423
Constant	4.960	4.123	1.447	1	**.229**	142.547		

In the final model, 'model four', all Glamorgan sub-items which proved to be significant in the univariate analysis were entered, in combination with the other significant general risk factors that were mentioned above in 'model three'. The overall model was statistically significant, χ^2 *(9, N= 70) = 15.26, P= 0.033*. This value indicates that the model was a better prediction than the zero block model (the null hypothesis). It was able to differentiate between patients who developed PU and those who did not in terms of their risk. The full model explains 19.6% (Cox and Snell R

square) and 30% (Nagelkerke R square) of variance, and has the ability to correctly classify 77.1% of the cases studied.

The only predictor which was shown to be significantly related to PU development in this sample was the time that a patient had spent on MV. Patients who were on MV, for four days or longer, were at six times greater risk of PU occurrence than the PU-free patients. (See Table 4.24)

Table 4.24: Model Four/ Glamorgan sub-items and General risk factors

Variables	B	S.E.	Wald	*d.f*	Sig.	Exp(B)	95% *C.I* for EXP(B)	
							Lower	Upper
Age in days	-.328	.498	.433	1	**.510**	.720	.271	1.913
ICULOS	.341	.501	.461	1	**.497**	1.406	.526	3.757
GCS	-.517	.338	2.339	1	**.126**	.596	.308	1.157
PEEP	.075	.153	.239	1	**.625**	1.078	.798	1.456
Duration on MV *	1.855	.935	3.939	1	**.047**	6.394	1.023	39.95
G6	16.776	40192.981	.000	1	**1.000**	1.931E7	.000	.
G1	-.035	.083	.174	1	**.676**	.966	.821	1.136
Constant	-11.772	40192.981	.000	1	**1.000**	.000		

***** Significant Variables (P≤ 0.05)

4.3.3 Predictive Validity of the Paediatric Risk Assessment Scales Used

4.3.3.1 The Glamorgan Risk Assessment Scale

For the purpose of determining the predictive validity of the Glamorgan RAS, the area under the ROC was calculated (AUC) (Figure 4.3). The AUC for the total Glamorgan scores was 0.79 (95% CI, 71- 87). Only the sub-items *mobility* and *equipment presses on skin* were significant in predicting PU risk. AUC= 0.69 (95% CI, 0.56-0.83), 0.71 (95% CI, 0.63-0.80) respectively. (See Table 4.25)

Table 4.25: The AUC of the Glamorgan total score and its sub-items

Test Result Variable(s)	Area	Std. Error	Asymptotic Sig	Asymptotic 95% *CI*	
				Lower Bound	Upper Bound
Mobility Glamorgan	.693	.069	**.006**	.557	.828

Equipment pressing on skin	.714	.045	**.002**	.625	.802
Significant anemia (Hb<9g/dl)	.471	.066	.681	.341	.601
Persistent pyrexia (Temperature> 38.0C˚ more than 4 days)	.490	.068	.881	.356	.624
Poor peripheral perfusion	.469	.066	.653	.339	.598
Inadequate nutrition	.625	.057	.073	.513	.737
Low serum albumin (< 35g/l)	.490	.069	.884	.355	.624
Weight percentile less than 10th	.583	.071	.232	.445	.722
Incontinence	.553	.074	.447	.408	.698
Glamorgan total risk score	.787	.042	**.000**	.705	.869

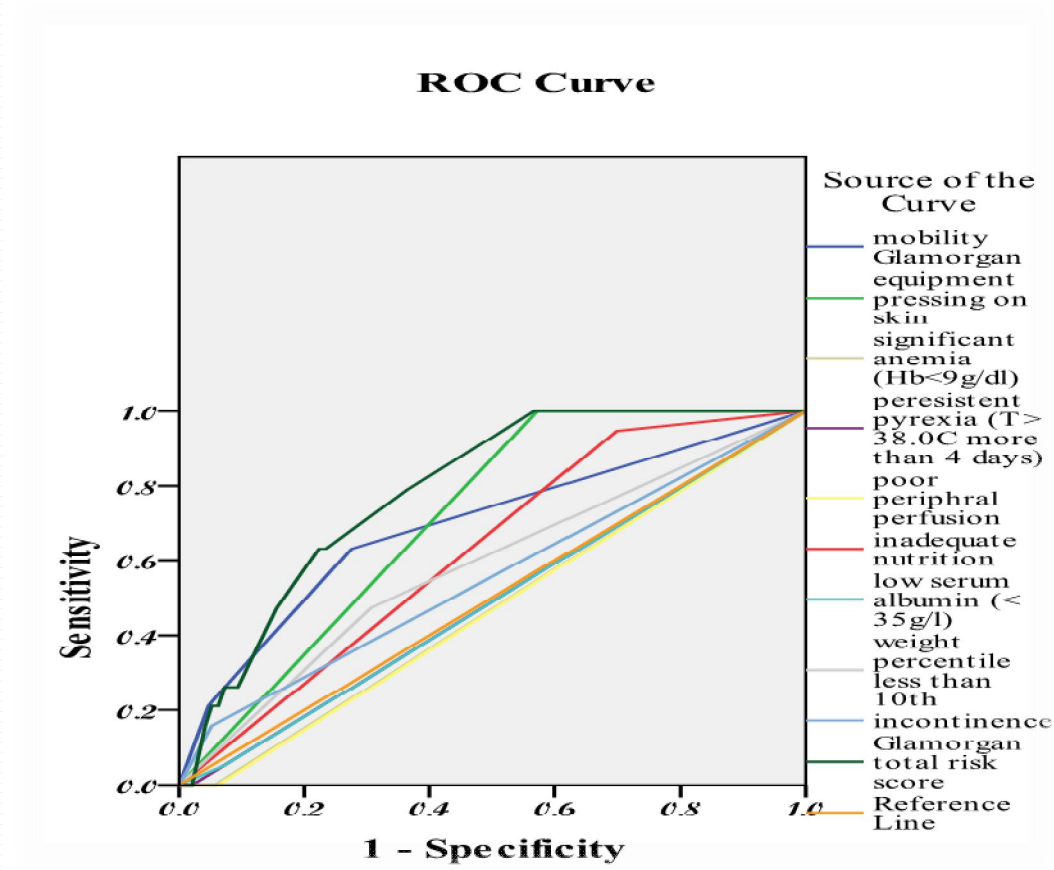

Figure 4.3: AUC for the Glamorgan Scale

a) Sensitivity and Specificity/ Predictive values

The sensitivity and specificity of the scale's total risk score were calculated. Sensitivity is the ability of the scale/ test to truly identify cases with the condition (PU-patients). It is equal to the True Positives Ratio (Anthony, 1996).

$$\textbf{Sensitivity Ratio} = \frac{\textbf{True Positive cases (TP)}}{\textbf{True Positive cases (TP) + False Negative cases (FN)}}$$

Specificity, on the other hand, is the ability of the scale/ test to truly distinguish patients who would remain free of the condition from those who would have the condition (PU-free patients). It is equal to the True Negative Ratio, and its purpose is to identify normal cases (Anthony, 1996).

$$\textbf{Specificity Ratio} = \frac{\textbf{True Negative cases (TN)}}{\textbf{True Negative cases (TN) + False Positive cases}}$$

For the Glamorgan scale, using the *Cross-tabulation method*, both values were calculated based on the cut-off score value (≥10). (Table 4.26).

Table 4.26: Glamorgan Risk classifications and PU Incidence

			Glamorgan level of risk				Total (N=212)
			0 no risk (< 10)	1 risk (10+)	2 high risk (15+)	3 very high risk (20+)	
Ulcer development (Incidence)	**0 Did not develop ulcer**	Count	74	8	69	42	193
		Expected Count	67.4	7.3	69.2	49.2	193.0
	1 Developed ulcer	Count	0	0	7	12	19
		Expected Count	6.6	.7	6.8	4.8	19.0
Total		Count	74	8	76	54	212
		Expected Count	74.0	8.0	76.0	54.0	212.0

Sensitivity= 19/19+0= 1 (100% sensitive based on risk score 10+).

Specificity= 74/74+119= 0.38 (38% specific based on risk score 10+).

A further two measures which were calculated were the positive predictive value (PPV) and the negative predictive value (NPV). The predictive values are interested in measuring the probability that the scale will give a correct diagnosis. In this study, it is the scale ability to correctly give a risk assessment classification. PPV is the proportion of cases which tested positive and were correctly diagnosed, while NPV is the proportion of cases which were negative on testing and were correctly diagnosed (Altman and Bland, 1994). Therefore, in this study, PPV is the proportion of children who were identified at risk on the assessment scale and were correctly classified at risk (actually developed PU). On the other hand, NPV is the proportion of children who were classified by the RAS as NOT at risk and were correctly free of PU.

PPV= TP/ TP+ FP, Glamorgan PPV= 19/ 19+119= 0.137 (13.7%)

NPV= TN/ TN+ FN, Glamorgan NPV= 74/ 74+0= 1 (100%)

However, these values are highly related to the prevalence rate, while the sensitivity and specificity values are not. When the prevalence rate is low, we would be more certain that the negative test truly indicates the absence of the disease (PU occurrence) (Anthony, 1996, Altman and Bland, 1994). In this study, the incidence was slightly low (9%), hence the high NPV.

4.3.3.2 Predictive Validity of the Braden Q Risk Scale for Paediatrics

Using the ROC curve, the AUC was calculated for the Braden Q RAS (Figure 4.4). The result showed that this scale's total risk score had a slightly superior AUC value to that of the Glamorgan RAS. The AUC was 80% (CI 95%, 76-89). The AUC was also calculated for all other sub-items. All were shown to have significant *P* values (≤0.05), except *Nutrition* (*AUC= 57%, P= 0.31*). (See Table 4.27)

Table 4.27: The AUC of the Braden Q total score and its sub-items

Test Result Variable(s)	Area	Std. Error	Asymptotic Sig.	Asymptotic 95% *CI*	
				Lower Bound	Upper Bound
Mobility Braden Q	.701	.070	**.004**	.564	.837
Activity level	.786	.035	**.000**	.716	.855
Sensory perception level	.780	.044	**.000**	.693	.866
Skin moisture	.774	.054	**.000**	.668	.880
Friction and shear	.735	.050	**.001**	.636	.834
Nutritional condition	.571	.057	.305	.459	.684
Tissue perfusion and oxygenation	.660	.059	**.021**	.545	.775
Braden Q total score of risk	.801	.044	**.000**	.715	.887

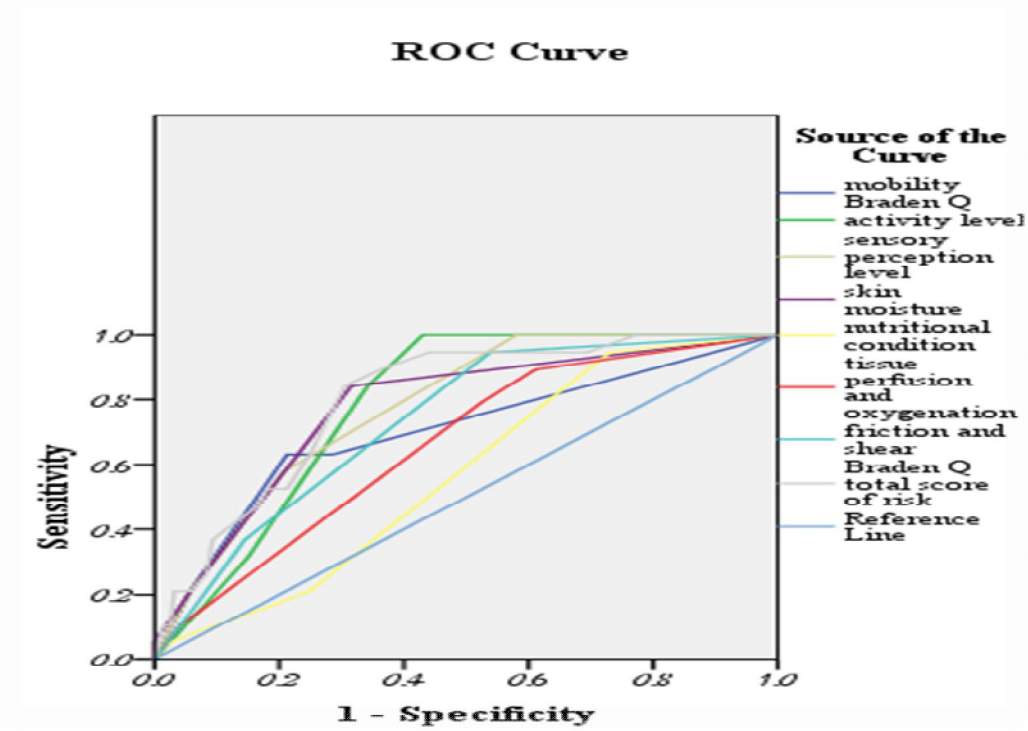

Figure 4.4: AUC of the Braden Q Scale

a) Sensitivity and Specificity/ Predictive Values

Sensitivity, specificity and predictive values were also calculated based on the Braden Q risk scores (cut-off score ≤16). (Table 4.28)

Sensitivity= 9/ 9+10= 0.47 (47% sensitive, 16 cut-off score)

Specificity= 161/ 161+32= 0.83 (83% specific, 16 cut-off score)

PPV= 9/ 9+32= 0.219 (21.9%)

NPV= 161/ 161+10= 0.941 (94.1%)

Table 4.28: The Braden Q risk classifications and PU Incidence

			Braden Q risk score		Total (n=212)
			0 no risk	1 at risk	
Ulcer development (Incidence)	**0 Did not develop ulcer**	Count	161	32	193
		Expected Count	155.7	37.3	193.0
	1 Developed ulcer	Count	10	9	19
		Expected Count	15.3	3.7	19.0
Total		Count	171	41	212
		Expected Count	171.0	41.0	212.0

4.4 SUMMARY OF THE CHAPTER

This chapter was a documentation of the main findings which resulted from the use of different statistical tests, namely descriptive, univariate and multivariate inferential statistical tests, and the ROC. The findings relate to different variables which were used in each statistical test.

The main aims of performing a statistical analysis were to be able to answer the research questions, to test hypotheses, and to identify the related risk factors of PU development in children admitted to ICUs. Also, by using the ROC, the performance of both scales used was tested. Their predictive abilities were measured and compared.

The use of descriptive analysis (frequency, mean, median, percentages), provided a general overview of the selected sample demographics and characteristics. Univariate analysis tools used were the *Chi Square* χ^2 test, *Fishers' Exact* test, the *Mann-Whitney U* test, and the *independent samples t*- test.

Seventeen different IVs were shown to be significantly associated with PU development in this population: 'being on MV', 'GCS', 'time patient spent on MV', 'PEEP level', 'age in days', 'ICU LOS', and the *mobility*, *equipment* and *nutrition* sub-items of the Glamorgan scale, in addition to the Glamorgan and Braden Q total risk scores, and all sub-items of the Braden Q scale except *nutrition*.

However, use of *LR* revealed only one significant predictor of PU development: 'duration of 4 days or longer on MV'. While the mobility sub-item of the Glamorgan scale proved to be significant in *LR*, none of the Braden Q sub-items were.

Use of the ROC revealed a slightly superior performance of the Braden Q RAS over that of the Glamorgan RAS. Yet, the sensitivity of the Glamorgan scale, based on a cut-off score of ten or more was much better than that of the Braden Q (100% vs. 38%). Using a cut-off score of 16 for the Braden Q, as recommended by authors (Noonan et al., 2011), might be clinically unacceptable. On the other hand, the specificity of the Braden Q was far superior to that of the Glamorgan scale (83% vs. 38%) using the same cut-off scores for each scale.

CHAPTER FIVE:

DISCUSSION

5.1 A GLANCE AT THE CHAPTER

This chapter addresses the methodological and statistical considerations of the research conducted, while also simplifying and clarifying the numerical findings given in the results chapter. First of all, the advantages and disadvantages of using the proposed methodology and study design are discussed, and the limited ability of some variables to explain the results is considered. Secondly, the uniqueness of this research in comparison with previous studies on the same area of interest is assessed. Next, the major findings will be discussed in light of the selected theoretical framework's major concepts and propositions and, finally, the key results will be compared with previous literature regarding the size of the PU problem among paediatrics, and more precisely its incidence among critically ill paediatric patients, as well as the PU risk factors, and the predictive validity of the utilised RASs.

5.2 METHODOLOGICAL CONSIDERATIONS

This section of the chapter highlights some of the methodological issues related to the study's research design, and the research questions. The novelty and uniqueness of the research methods used here are compared with other PU risk assessment studies, as well as previous paediatric incidence and prevalence studies.

The strengths and weaknesses of the chosen research method are underlined in relation to its ability to clarify the relation between the studied risk factors (set of specified predictors) and the observed outcome (PU formation), and the predictive validity of the two scales is determined, based on a longitudinal prospective design.

Although PU has been reported as a problem which affects children in many previous incidence and prevalence studies (Willock et al., 2000, Zollo et al., 1996, Curley et al., 2003a, Dixon and Ratliff, 2005, Fujii et al., 2011, Huffines and Logsdon, 1997, McLane et al., 2004), none of these were conducted in Arab countries. So, this research is the first of its kind to discuss PU in paediatrics in both Jordan and the wider Arab world, as well as the fourth dealing with PU generally in Arabic countries (Saleh et al., 2009, Abou El Enein and Zaghloul, 2011, Tubaishat et al., 2011), and the second in Jordan (Tubaishat et al., 2011).

Moreover, the prevalence and incidence results of this study could be used as benchmarking data in Jordanian hospitals on the size of the PU problem in paediatrics. This, as mentioned in previous literature, is important for allocating health care resources, saving money and effort, and improving quality of care for patients (Cockett, 2002, Kottner et al., 2010, Noonan et al., 2011). Also, it could help in adopting a PU risk assessment scale, especially designed for paediatrics in Jordanian hospitals, which would offer an alternative to the adult Braden scale which is used currently.

In addition, the incidence study in this research is one of only a few studies which have assessed risk factors using a longitudinal prospective design (Zollo et al., 1996, Willock et al., 2000, Curley et al., 2003a, McCord et al., 2004, Fujii et al., 2011). Several paediatric studies have explored factors related to PU development based on cross-

sectional designs (Suddaby et al., 2005, Dixon and Ratliff, 2005), while others have centred on reviewing patients' medical records (Schluer et al., 2009, Neidig et al., 1989, Murdoch, 2002), or have applied retrospective designs (Manning and Curley, 2012, Samaniego, 2004, Neidig et al., 1989, Schindler et al., 2007). In general, these studies lack satisfactory explanations of the methods used, adequate sample sizes, or good enough descriptions of the statistical analyses.

Next, this study is unique in that it uses data collected prospectively to compare the predictive performance of two paediatric risk scales over critically ill PU and PU-free patients. One study (Anthony et al., 2010) compared the predictive validity of three paediatrics RASs, the Braden Q, Glamorgan and Garvin, yet it was retrospective. Another recent study (Long et al., 2011) compared the performance of the Glamorgan and the Braden Q scales. However, although it was prospective, it lacked adequate reporting of the research methods and the study's main findings, since it was a poster abstract.

Comparing this thesis with the solely identified prospective incidence study (Long et al., 2011) revealed the uniqueness of the studied sample, the critically ill children and neonates. Moreover, Long et al. (2011) did not aim to study the predisposing factors of the paediatric patients' PU risk, while this thesis does.

In last, the prospective design enabled the Glamorgan scale's performance to be tested on another population (Jordanian ICU patients), as recommended by the scale developers, since the previously identified research study designed to test the scale's predictive ability, was performed on the same sample set that was initially used to develop the scale (Willock et al., 2009).

For the Braden Q RAS, this study also enhanced the scale by testing its predictive validity on large groups of children and neonates of different ages, as recommended previously (Noonan et al., 2011). More specifically, the Braden Q scale was tested on neonates and premature babies, as well as on children aged over 8 years old in this thesis, whereas previous studies had used the Braden Q scale on children aged only

from 21 days up to 8 years. In addition, this research work aimed to identify how the scale would perform if used to predict device-related ulcers.

5.3 STATISTICAL CONSIDERATIONS

Having a large set of predictors (risk factors/ IVs) demanded the use of a variety of statistical approaches. More than 40 predictor variables were analysed by several descriptive statistical tests calculating frequencies, percentages, means and standard deviations. Moreover, these predictors were tested using both univariate and multivariate analyses, as detailed in the Results Chapter.

The use of univariate tests identified a preliminary set of significant predictors of PU in this population (children and neonates in ICUs), before an extra step was performed by using *LR* test to reveal a more accurate set of PU predictors. The use of this advanced form of analysis enabled the researcher to obtain more statistically accurate results. Using all these types of statistical analyses on the collected data may offer a significant contribution to our knowledge and understanding of paediatric PU.

Logistic regression was performed using the *Entry* (Enter) method on SPSS. In this default method, the predictors are entered all together in one block, without any one predictor being given priority over the others. This approach has been recommended by statisticians to test theories, or when there is no previous knowledge about the order or the importance of one variable over others (Field, 2009, Tabachnick and Fidell, 2007, Marston, 2010).

The *Entry* method was necessary in the current research because of the researcher's intention to test all risk factors simultaneously, without giving any of them a pre-specified priority over the others, in order to ensure an equal chance of investigation for all variables. The *Entry* method is sometimes preferred because all variables would be included and retained in the model. This is especially the case when dealing with dummy variables - or categorical variables coded as 0 and 1 in regression models using SPSS - because in other regression methods like *Stepwise*, a dummy variable may removed if one of its sub-categories is not significant, even if the variable as a whole is

significant. However, dummy variables which have at least one significant category should be retained in the model as a whole (Marston, 2010).

Conversely, the *Entry* method may cause some difficulty for data interpretation since a predictor which correlates strongly with the observed outcome, may actually show little predictive capability if entered with other predictors simultaneously (Field, 2009). However, the use of another *LR* method, *Stepwise*, may also have its limitations. That is, this method might cause statistical errors as findings are interpreted; because of the risk of omitting variables based on statistical criteria such as Wald statistics, or the Likelihood Ratio.

For the latter method of regression, some variables could be significant but only removed of the built model by another variable based on these criteria (Tabachnick and Fidell, 2007). Nevertheless, this method was also applied to the same set of predictors for this study sample, in order to ensure no possible significant predictors of PU occurrence were missed. No extra benefit was obtained by using this method, however, since the same significant risk factors were identified by both the *Stepwise* and *Entry* methods.

5.4 THE IMPACT OF THE THEORETICAL FRAMEWORK ON THE STUDY'S MAIN FINDINGS

This section introduces the findings of the current research work based on the adopted theory, the SDT. In first, the identified previous health- related studies are presented, with explanation of the way of applying the SDT to their main inquiries, next; the application of this theory major concepts and assumptions on the current work general context and themes was addressed, and finally; how these concepts and propositions were used to highlight the findings of this research work was provided.

5.4.1 Previous Implications

Many disciplines, such as psychology, mathematics, medicine, and radar studies, use SDT in their research. In medicine, it is used in diagnostic related studies and, in nursing particularly, for risk assessment studies. One study combined SDT with the

high reliability theory to produce a new theoretical framework, called the detection of patient risk theory (Despins et al., 2010). The framework sought to describe how nurses would perform in detecting patients' risk, in view of health organizations' patient safety policies.

The way in which nurses would detect any sign of patient risk from the surrounding environment was based on the SDT, and then their responses were assessed, though, nurses' decisions would be greatly influenced by the health organisation's manner of dealing with and protecting patient safety issues (Despins et al., 2010).

Nurses would try hard to detect factors which predispose patients to risk, although their ability to do so was affected by the hospital's degree of reliability. Therefore, nurses' response to risk signals would be improved by patient safety being a priority (Despins et al., 2010). It was also claimed that the nurses' level of sensitivity in detecting risk would affect their ability to identify actual risk. However, sensitivity was thought to be a learned process which would be affected by a nurse's level of knowledge, training, and experience, as well as internal factors, such as fatigue, and the effect of the complexity of the ward and hospital environment (Despins et al., 2010).

Another study (Thompson et al., 2008) investigated the effect of time pressure and experience on nurses' ability to take risk assessment decisions. Through the use of SDT, it was shown that nurses under pressure in acute care units had low sensitivity in detecting patient risk, while in cases where there was no time pressure, nurses with longer experience were observed to have improved abilities to detect patients at risk and intervene properly. According to the study, under time pressure circumstances, nurses in acute care wards would perform poorly in regard to assessing patients' risk, and hence intervene less efficiently to avoid the hazard.

5.4.2 SDT Context within the Current Research

This theory helps to explain how an observer can take a decision in uncertain situations (Wickens, 2001), such as when assessing patients' risk of developing conditions like PU. Taking decisions about risk is uncertain, because predicting an event's chance of

occurrence is not the same as it actually happening. So, in classifying patients into risk or no risk groups, not all patients who were classified as being at risk would actually develop PU.

The main goal for nurses is to predict patients at risk of PU formation as early as possible, and intervene accordingly to prevent the occurrence of PU or to avoid further skin damage. The use of a RAS also helps to classify patients into risk groups based on a specific criterion, or a pre-specified threshold, or cut-off score, and then apply prevention measures as applicable.

It is crucial for nurses to detect children at actual risk of PU occurrence correctly and, at the same time, to reduce effort and prevent resources being wasted through the improper application of preventative interventions for those not at risk, and who would not develop PU. In other words it is crucial to have a very sensitive and specific tool.

If a person can easily distinguish true signals from surrounding noise, he can correctly take decisions about a condition's chance of occurrence. That is, if nurses (Observer) can easily recognise true risk factors of PU (Signals) in critically ill paediatric patients over irrelevant factors (Noise), then they can classify children at risk successfully (Decision), and so can intervene reasonably, avoiding time and effort being wasted on false classifications.

However, even if the nurse was able to correctly distinguish true risk factors from other irrelevant factors, and he/she was able to confirm that particular patient's risk, this might be not enough trigger for nurses to take preventive actions. According to the theory it could be true that identifying correct signals of risk would help in correct classifications of patients into risk or not risk groups efficiently, yet, this is not enough to guarantee nurses taking prevention and management actions.

The theory reflects the need of correct identifying of risk factors to classify patients as risk, but the direct impact of this true classification was not reflected on the actual nurse practice and the true triggers of nurses to apply prevention properly. In fact, if a nurse was aware of the true patient risk of PU formation and did not take any action to prevent

this risk this would be unethical in clinical practice and would result in further time and resources wasting.

Despite the fact that identifying signals of particular conditions is, in many cases, straightforward, taking decisions based on the appearance of any of these signals is difficult. For example, one nurse might identify immobile children as being at risk of PU development on the basis of his or her experience and previous knowledge that immobile children are known for being unable to control their body position, and to respond to pressure or pain appropriately, which would increase their PU risk. However, she or he cannot say for certain that any immobile child would develop PU.

In previous example, the nurse can distinguish immobility as a true warning signal of PU development, although, alone, this would not be enough to base a decision about patient risk on. On the other hand, although a decision in itself is distinctive (patient at risk or not at risk), contributing factors are not distinctive, and sometimes they might be contradictory or overlap. For instance, some nurses may believe that children who have dry skin are at risk of PU, whereas others might believe that excessive moisture on the skin would increase the risk of ulcers developing.

5.4.3 The Main Concepts of the SDT and the Current Research

A description of how the main concepts of the SDT can be defined in relation to this thesis is offered below;

- ***The Stimuli:***

The stimuli in this study are the group of identified contributing factors for PU development. The true signal is an actual significantly related risk factor or predictor of PU development. On the other hand, the noise is any factor present in the patients' environment or related to their health condition which appears as if it may be a contributing factor for PU development, but actually is not.

- ***The Observer:***

The nurse, or the RAS which is used by the nurse, is the observer. The nurse, as an observer of stimuli, needs to have the ability to take the correct decision by detecting true signals among false stimuli. However, this ability depends on many factors, including nurses' training, degree of experience, and level of knowledge. It also depends on factors related to the observer's physiological condition, such as their level of fatigue, at the time of decision making (Wickens, 2001), since fatigued nurses tend to have more negative responses to stimuli (deciding there is no risk), compared with non-fatigued nurses (Wickens, 2001). For example, a nurse with a very busy schedule working in a noisy environment may be too tired to notice any threat to patient safety.

Nurses, in many cases when uncertain, tend to choose the easiest way of responding by classifying more patients as not at risk, to conserve time and effort. On the other hand, nurses with a less demanding workload may prefer to classify patients as at risk for a condition even when they are not completely sure, and intervene according to this choice, which may take more time and energy, rather than to predispose patients for possible risk (Wickens, 2001).

According to SDT, the observer's ability to detect signals correctly is called sensitivity. Thus, nurses' training and knowledge, and their physical condition, affects their sensitivity level. Also, the use of an RAS by the nurse affects sensitivity, since a well defined scale which is able to correctly classify children who are at risk of PU is considered more sensitive.

From another perspective, in SDT, the strength of the signal also affects the observer's sensitivity (Wickens, 2001). When the signal is stronger, it is easier for the observer to detect. Here, nurses can more accurately detect risk factors when the patient has stronger/ more obvious characteristics of PU risk. For example, an immobile patient who is ventilated for a week and with restricted positioning' times, would be at higher risk of PU development than an ambulant child with a mild respiratory infection.

Similarly, when nurses use risk scale to classify patients at risk of PU development, patients with higher risk scores might have a greater chance of developing ulcers than those who had lower scores, the highest risk scores are stronger indicators of PU development than the lowest scores (and vice versa for the Braden Q RAS). Yet, this is correct when the scale is able to correctly classify patients into risk groups, if the scale total score, or any of its sub-items show no real difference between PU risk patients and those who are free or risk, then these scores would not be beneficial in reflecting these patients true risk.

Observer sensitivity is also seen to be affected by the amount of existing noise surrounding the true signal (Wickens, 2001). In this case, if an actual risk factor for PU development is hidden by a very large number of surrounding irrelevant factors, it would be more difficult for the observer nurse to correctly identify this factor, and thus he/she would encounter greater difficulty in classifying patients at risk. This might cause the nurse's decision to be less sensitive, and predisposed to error (false positives and false negatives).

For example, an ICU nurse could be very confused by the large number of PU risk factors or predictors of patients present in the ICU environment, such as being on MV, sedated, immobile, malnourished, on specific medications, having certain deficiencies, or abnormal laboratory test results. However, this assumption supports the use of RAS, since using a pre-specified checklist or RAS would decrease the number of possible predictors of PU in ICU patients, allowing the nurse to be more focused and to more easily ignore factors that hide the true risk.

Moreover, using the rule of thumb to validate any risk assessment scale, the researcher would need at least 10 cases for each risk factor so the findings would be true (Coleman et al., 2013). Yet, this would be very difficult to implement in paediatric PU cases, since this problem in this population is not very prevalent, which would require hundreds of PU patients to validate any existing RAS.

In spite of this, if the scale was not originally predictive, or included irrelevant factors (noise rather than true signals), this may mean that it would be less sensitive and the

nurse's decision would consequently be incorrect, thus putting children at greater risk of PU development, and decreasing their chance of proper intervention and of PU being prevented.

Therefore, the theory also supported the current study's research question in regard to the predictive validity of the two paediatric RASs used. That is to say, it has shown why it is important to pursue this inquiry in the field of PU assessment. Testing the scales' ability to predict risk, using the AUC of the ROC, sensitivity and specificity values, is crucial in determining whether the use of these scales in the medical field should be supported.

- ***The Response:***

The nurse's response could be one of four possibilities: false positive, false negative, true positive and true negative. These values were discussed in the Results Chapter. When a nurse uses her clinical judgment, or uses a RAS, these are the four possible responses:

SDT	NURSE	STATISTCALLY
Hit	Child who had been classified at risk, did develop PU	True positive
False alarm	Child who had been classified at risk, did not develop PU	False positive
Correct rejection	Child who had been classified not at risk, did not develop PU	True negative
Miss	Child who had been classified not at risk, did develop PU	False negative

Based on the SDT, *h ratio* (hits ratio), and *f ratio* (false alarm ratio) are important, because they complement each other. It is necessary to calculate these values to have a full picture of the situation in which the nurse takes her decision. In our research, to test the predictive ability of the two used scales, these values were calculated.

The *h ratio* is the same as the sensitivity, and *f ratio* is the same as the 1- specificity. These two values are crucial in calculating the AUC, which tests the scale's

performance in the ROC curve. The *f ratio* and *h ratio* are both significant values, to measure the performance of any scale on different cut-off scores or thresholds. Specificity and sensitivity values were calculated for the RASs used in the current study in the results' chapter, and are discussed more later in (section 5.5.3) of this chapter .

As previously discussed in the literature chapter, each observer has a specific criterion on which their response depends. In this study, each scale's cut-off score was the criterion (≥ 10, Glamorgan and ≤16, Braden Q). If the patient achieved a score higher than the criterion (or lower in the case of the Braden Q), the observer would respond with 'Yes' or, in other words, the child would be classified as at risk of PU. Conversely, if a child obtained a score lower than the criterion, the observer's response would be 'No', which meant they were not at risk of PU. However, in situations where nurses use their clinical judgment alone, without reference to a specific RAS, the criterion for each nurse would be subjective, based on their own experience and knowledge. Hence, there exists much variation in classifying children at risk of PU based on clinical judgment alone.

Any attempt to increase the observer's hits will reduce the number of correct rejections, so increasing the *h ratio* would decrease the *correct rejection ratio (1- f ratio)*. This is also true in the current study where trying to improve the sensitivity of the scale would diminish the specificity, and vice versa. Therefore, researchers usually try to choose a threshold (criterion) for classifying patients, in which the scale would perform the best in both sensitivity and specificity values.

In summary, the nurse (the observer) would encounter an uncertain situation (is the patient at risk of PU development or not?) and he or she would try to take a correct decision regarding risk classification (at risk or not at risk), by accurately detecting the signal (true risk factors for PU development) amid any surrounding noise (irrelevant factors in the hectic environment of the ICU). This decision would be based on a pre-specified criterion (the nurse knowledge and/or the RAS cut-off score). The nurse's response would be correct (a true positive or true negative) or incorrect (a false positive or false negative), although detecting positive cases (children with PUs) correctly is the priority for nurses.

Using sensitive and specific RAS might improve nurses' ability to detect PU risk in critically ill children, by reducing the amount of noise (irrelevant factors). The RAS should have a cut-off score (criterion) which makes it more sensitive, but not less specific. Sensitivity is crucial in order to identify the number of children who are at actual risk of PU development, and so reduce any further skin damage, suffering or pain for these children. On the other hand, specificity is crucial to ensure the appropriate allocation of health resources, and prevent time, effort, and equipment being wasted.

The following Figure (5.1) illustrates the SDT framework's application to the current study:

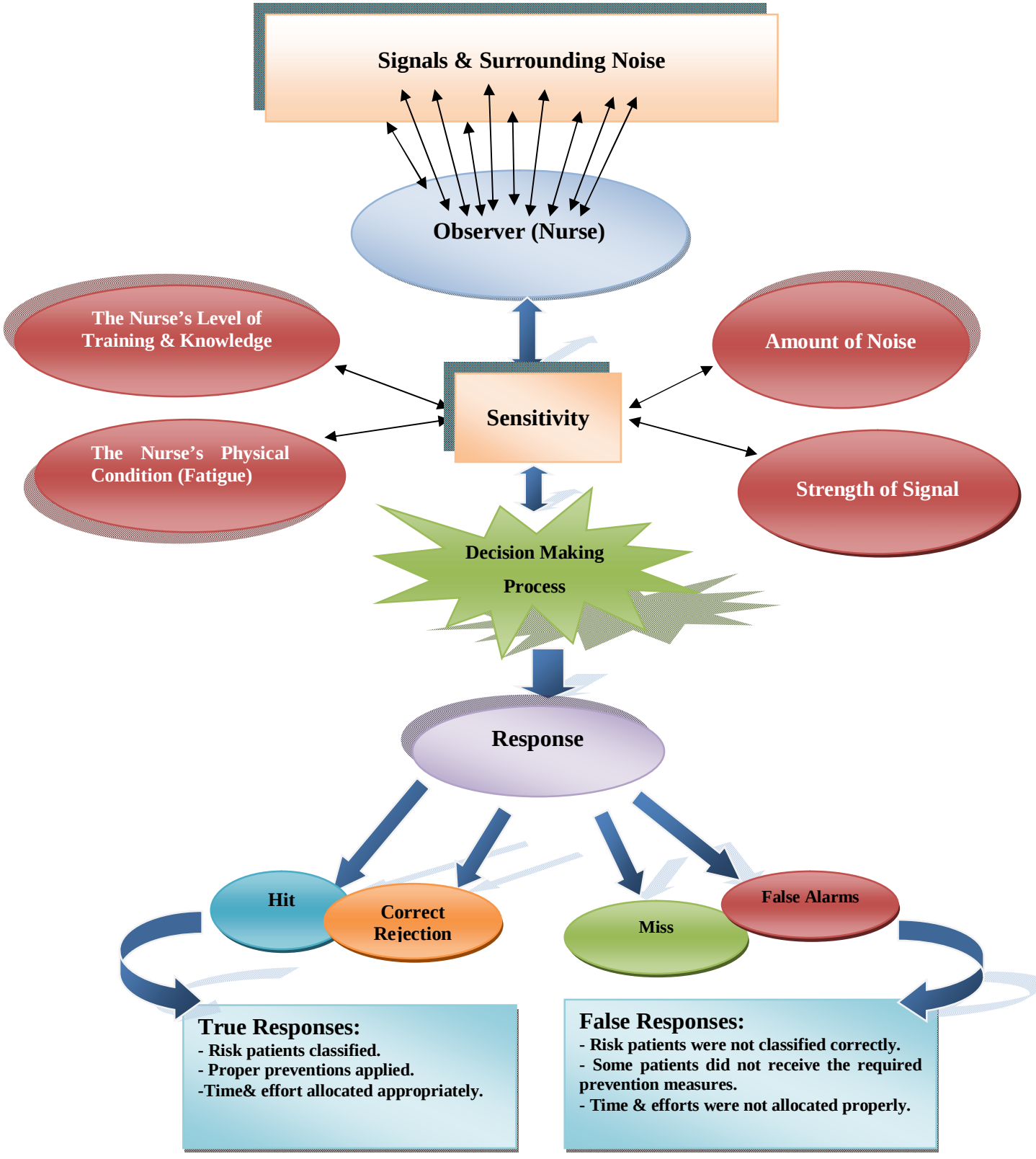

Figure 5.1: The SDT's Application to the Main Findings of the Research

5.5 INTERPRETATIONS OF THE STUDY'S MAIN FINDINGS

5.5.1 The Prevalence Study

This section of the chapter discusses the major findings of the point-prevalence survey, including the prevalence rate, characteristics of children who had PU, the major sites of PU, categories and numbers.

5.5.1.1 The Prevalence Rate

The prevalence rate (7.5%, n= 8) was similar to that reported in some previous prevalence studies in paediatrics. Willock et al. (2000) found a prevalence rate of 6.5% (n= 12) among 183 children admitted to one hospital in the UK, However, Willock et al. included blanchable erythema in PU classification, as category *I*. Excluding this category would decrease the prevalence rate to 2.1% (n= 4).

One further study (Noonan et al., 2006) which was carried out in a tertiary university-affiliated hospital documented a PU prevalence rate as low as 1.6% (n= 4), despite the setting for this research being very similar to that of our current study. However, the prevalence rate would be similar to the current study's if combined with the prevalence of device-related ulcers (6.7%, n= 17).

Regardless of the fact that Noonan et al. (2006) considered device–related ulcers to be another type of skin breakdown, of the total 252 assessed patients, ten patients had ulcers from the use of a pulse oximeter, and three more from other medical devices. In the current study, the prevalence rate would be only 2.8% (n= 3) if device-related ulcers had been excluded.

The work of Nie (2008) also supports the findings of this thesis in a study of 266 paediatric patients in one hospital, which found a PU prevalence of 10.7% (n= 22), 19 of these were facility-acquired ulcers (9.2%).

On the other hand, in one large prevalence survey (McLane et al., 2004) of 1064 children in 9 hospitals in the USA, only 43 patients were found to have PU (4%). However, the researchers found a higher prevalence rate of other types of skin

breakdown such as extravasations, diaper dermatitis, and plaster injuries, and the calculated prevalence rate for all types of skin injuries combined was 18.9% (n= 201).

Another study (Dixon and Ratliff, 2005) reported similarly low prevalence rates to McLane et al. (2004), of only 3% (n= 2 out of 77) and 4% (n=3 out of 79) respectively in two prevalence studies, which took place one year apart. However, these surveys were conducted in only five paediatric wards in one tertiary care university hospital in the USA, which might affect the estimation of the actual size of PU in this population.

Baldwin (2002) reported a much lower prevalence rate of PU in her mail survey of 234 staff members of four USA health care databases. Prevalence data obtained relating to PU in paediatrics revealed the prevalence rate to be just 0.47% (21 of a total 4429 paediatric inpatients had PU). However, the low response rate of the survey (25%, 51 questionnaires), may have affected the credibility of the findings.

By contrast, higher prevalence rates have also been documented in the literature. One multisite study, for example, which was conducted in four paediatric institutions in Switzerland, uncovered a relatively high PU prevalence rate, where 43 out of 155 assessed patients had PU (27.7%). However, this rate dropped to only 4.5% (n=7) when category *I* PU (non-blanchable erythema) had been excluded (Schluer et al., 2009).

As seen in this section, including *category I* PUs or excluding them has its effect on the variation in PU prevalence rate in paediatric population. In fact, such category is described in many credible PU classification systems worldwide, such as the one used here the EPUAP classification. Ignoring such type of ulceration from prevalence and incidence studies might underestimating the actual size of the problem, and hence improper prevention might be applied for patients suffering from such category of ulceration and this might put them at higher risk of further damage in their skin into more sever categories of ulcers.

5.5.1.2 Most Affected Sites

Several paediatric PU prevalence studies agree that the head (mainly the face and occiput) is the site most commonly affected with PU (McLane et al., 2004, Willock et

al., 2000). This is supported by the results of the current study, which found that, of the 13 observed cases of PU, five were in the face (38%), jointly followed by occiput and 'neck and shoulders' (n= 2, 15%). Yet, the most severe ulcers (category *III*) were found in the sacrum, occiput, and ankles (one ulcer in each site, 12.5%)

In McLane et al. (2004), 31% (n= 13) of PUs were located on the head, including the occiput, head-other and nose and ears. This was followed by the seat area (20%, n=9) and the foot area (19%, n= 8). Also, in Willock et al. (2000), the occiput and ears were among the primary locations affected by PU, as occiput was the first most affected site (n=4), followed by heel and ears (n= 3 patients for each). However, these findings were based on a mix of prevalence and incidence data, from studies conducted at the same hospital one month apart.

On the other hand, Suddaby et al. (2005) reported the buttock as the site most often affected by PU (31%, n=25), followed by perineum (24%, n=19), and occiput (10%, n=8). Around 88% of the occipital skin breakdown occurred among PICU patients (n=7).

Furthermore, Schluer et al.'s (2009) findings on sites of PU differ from those of most reports, as unspecified areas were documented as the most commonly affected with ulcers (43.1%, n=25) followed by heels (15.6%, n= 9), ankles and ears (10.4%, n= 6 for each). The unspecified areas could not be precisely described because the ulcers had mostly developed in areas next to which equipment such as drain tubes or monitor cables had been placed. However, the ears in their study were similarly mentioned in other prevalence study of paediatric PU (Willock et al., 2000).

By contrast, Baldwin (2002) found 'under the waist' ulcers to be the most dominant (78%, n= 16). Of these, the sacrum and coccyx were the most frequently affected areas (40%, n= 6), followed by heels (27%, n= 4). Otherwise, the 'above the waist' ulcers accounted for only 28% (n= 5) and in this group the occiput was the most predominant site of ulcer formation (65%, n= 3). Suddaby et al. (2005) also give buttocks, perineum and occiput as the locations most affected by skin breakdowns.

Another study (Dixon and Ratliff, 2005) named heels as the site affected by the highest number of PU cases, (50%, n=3). This was followed by one case of sacral PU, one ankle, and one in nares (17% for each). The nares (nostrils) are also one of the head areas that might be worst affected by ulcerations, due to the use of nasal continuous positive airway pressure (CPAP) in neonates specifically and in paediatrics in general.

One further study observed PU in the occiput and hands (Noonan et al., 2006). Two out of four PU-patients had occipital ulcers, and another one suffered from hand ulcers due to prolonged positioning in the OR, and one more had heel ulcer (Noonan et al., 2006). However, this study identified other types of skin breakdown, including those related to equipment pressing, such as nasal breakdown, and ulceration due to the use of a pulse oximeter. Since there is high variety in types of skin breakdown were mentioned in Noonan et al.'s study (12 including PU), none will be discussed here.

In a number of the previously mentioned studies (Waterlow, 1997, Willock et al., 2000, Dixon and Ratliff, 2005, Baldwin, 2002, Schluer et al., 2009, McLane et al., 2004), heels seem to also be a significant site for PU development in children as almost all of them list heels among the first three areas of the body that are most frequently affected by PU. In the current study, heel and ankle PUs were observed in two patients (15%).

5.5.1.3 Pressure Ulcer Categories

Most ulcers identified in paediatric PU studies have been of partial thickness, or, in other words, belonging to category *I* or category *II* (Willock et al., 2000, McLane et al., 2004, Baldwin, 2002, Noonan et al., 2006, Schluer et al., 2009). In the same way, 75% of all identified ulcers in this study were of partial thickness (n= 6). Of these, around 63% were category *I* (n= 5), and 12% (n=1) were category *II*. Two patients' ulcers were classified as category *III* (25%) and none were category *IV*.

Pressure ulcer categories *I* and *II* usually refer to non-blanchable erythema and superficial damage through the skin to the dermis (EPUAP and NPUAP, 2009). However, in some studies, category *I* has included blanchable erythema, where any redness to the skin, even if it blanches with a finger pressed against it, would count as a

PU. For example, this was the case in Willock et al. (2000). Other studies, however, do not detail their classification systems for PU classifications (Baldwin, 2002, Nie, 2008).

In Dixon and Ratliff (2005), non-categorised ulcers, in addition to category *I* PUs, were the most frequent, accounting for three ulcers in each category, of the total number of ulcers identified in the two prevalence surveys. Moreover, in Suddaby et al.'s (2005), 77.5% of skin breakdowns were erythema (n= 62), using the AHCPR staging guidelines, yet, they considered diaper dermatitis as category *I* ulcers.

5.5.1.4 General Characteristics of the PU-Patients

Of the 129 paediatric patients identified on the day of the study, 107 patients were eligible to participate (83%). Most PU- patients had single ulcers (50%, n= 4), three had two ulcers (37.5%), and one patient had three (12.5%). All except one of those patients had facility-acquired ulcers (87.5%, n= 7). Previous literature has shown that children usually suffer from multiple ulcers, without specifying the number of ulcers for each child. For example, 43 children in McLane et al' study (2004) had developed 64 PUs, whereas in Suddaby et al.'s study (2005) 80 children were documented to have 100 skin breakdowns.

In a very similar manner to this research, Willock et al. (2000) found that single ulcers had affected most children (17 out of 18) in their study, and only one child had suffered triple ulcers. However, Willock et al.'s findings were based on a mix of data from prevalence and incidence studies which were carried out a month apart. Another multi-site prevalence study (Schluer et al., 2009) also produced similar findings; of 43 PU patients, thirty four had single ulcers (79%), seven had two (16%), and two had five ulcers (5%).

In addition, like most of the ulcers observed in this research were facility-acquired, McLane et al. (2004) also reported that more than half of PU cases in one PICU were facility-acquired. Two more prevalence surveys, one multi-site and the other which took place in a university children's hospital, showed that all or almost all ulcers were facility-acquired respectively (Noonan et al., 2006, Schluer et al., 2009). Dixon and

Ratliff (2005) also stated that all observed ulcers were hospital acquired except one heel ulcer presented in one child on admission from another hospital.

As previously noted, it is clear that the vast majority of PUs affects children in hospitals rather than at home, this sheds light on the deficient prevention programs that are used in paediatric care current practice, also this emphasizes the need to establish unique PU assessment and prevention protocols, which fit precisely with children and neonates, according to each group's developmental needs.

Almost 88% of the observed ulcers in the current work belonged to patients in critical care units (n= 7). Only one case was observed in the surgical ward (12.5%), which was that of a 7-year-old boy who had been previously admitted to the PICU several times because he was left quadriplegic as a result of a road traffic accident (RTA). However, unlike in some of the paediatric prevalence studies (Waterlow, 1997, Willock et al., 2000, Schluer et al., 2009), no PU- patients were found in the medical wards.

Children in critical care units or who have been cared for in ICUs have been established in the literature to have a higher prevalence rate of PU (Willock et al., 2000, Dixon and Ratliff, 2005, McLane et al., 2004). More than a third of PU-patients were cared for in the ICU in one study (42% , n= 5) (Willock et al., 2000). In another (McLane et al., 2004) this was the case for around 14% of children affected with PU, and around 72% had stayed in ICU at least once during their single admission, with a prevalence rate of 8.7% specifically in ICUs.

One study (Schluer et al., 2009), conversely, found that most ulcers were observed in the rehabilitation unit (33%, n= 10), followed by surgical wards (30%, n= 10), neonatal wards (27%, n= 11), and medical wards (24%, n= 12). This was explained in relation to the nature of the patients in these units, who are immobile, in pain, or have delicate sensitive skin, which increases their risk of improper positioning and, in turn, of PU. Dixon and Ratliff (2005) also stated that most observed ulcers were identified in neonatal, PICU, and rehabilitation units.

Most of the PU-patients identified in this study were less than one year old (62.5%, n= 5), which mirrors results of previous research. For example, seventeen out of 43 PU patients in one study were one year old and younger (McLane et al., 2004), and 26% of these children were younger than 3 months old (n= 11). Similarly, three patients out of four who had occipital PU were less than one year old (Willock et al., 2000). In Schuler et al. (2009), around 85% of children who were classified as at risk for PU development were neonates (n= 35).

For the prevalence study sample of this thesis, the hospital LOS for PU-patients was significantly higher than that of PU-free patients (*U=174.5, p=0.008)*, with a median (IQR) of 11.5 (27) days versus 4 (7) for PU- and PU-free patients respectively. Paediatric patients with PU have been noted before to typically have longer periods of stay in hospitals. Schluer et al. (2009), for instance, stated that hospital LOS was the only significant difference between PU- and PU-free patients' characteristics, with a median of 25 days versus 9 days respectively (P= 0.019).

Interestingly, females were affected by PU development more than males in this study (62.5%, n= 5), despite the fact that males constituted the largest portion of the current sample (64.5%, n= 69). However, due to the small sample size, this was found not to have any statistical significance (*Continuity Correlation=1.6, d.f= 1, P=0.203*). Yet, no description of gender differences between PU-patients and PU-free patients were reported in previous literature so it was difficult to draw conclusions, or to either support or reject any propositions.

5.5.2 Incidence and Risk Factors Study

This section of the chapter discusses the major findings of the incidence survey. Based on a prospective cohort observational study, the incidence rate is estimated, the main affected sites are identified, and the most frequently observed categories of PU are discussed. Moreover, a separate part clarifies the most widely encountered contributing factors of PU development among paediatric patients in ICUs. These factors are discussed with reference to the previously observed PU contributing risk factors among

different paediatric populations, the different statistical methods used, and the research designs used.

Incidence studies play a significant role in the identification of new cases of a specified problem over a certain period of time within a specific population (Shields and Twycross, 2003). They are also thought to be important in locating any changes of a specified condition or problem over a period of time, and allow the findings of different studies to be compared more efficiently than in the case of cross sectional prevalence studies (Shields and Twycross, 2003).

For this study, incidence data was used to estimate the size of the PU problem over an eight week period among critically ill paediatric inpatients in Jordan. Studying risk using a prospective design was crucial for investigating the factors associated with PU risk in this population more accurately. Cross sectional designs identify factors that are found to exist concurrently with identified PU cases at one point in time. However, studies of this type cannot tell us if these factors precede PU development or if they really contribute to PU formation.

The factors described in cross-sectional design studies could be discussed as special characteristics of PU-patients but not as possible risk factors. In prospective studies, including PU-free patients and observing the development of PU over time could help to highlight the possible risk factors that lead to PU development.

However, the study of risk factors needs more rigorous study designs to reveal more robust and accurate findings. An example would be the Randomised Clinical Trials (RCTs), which are difficult to conduct in nursing studies, because of ethical dilemmas surrounding their use (Willock et al., 2009), these issues might include controlling some factors, such as holding medication or life supportive equipment to study their direct effect on children's skin, or withholding some of the preventive interventions to control their effect on the incidence rate or the validity of the used assessment scales.

5.5.2.1 Pressure Ulcer Incidence:

a) Incidence Rate

Nineteen out of a total of 212 children and neonates recruited from three ICUs in one university hospital developed 29 PUs (incidence rate of 9%). The rate was lower than that documented in previous literature, and more precisely in studies carried out in paediatric ICUs.

Willock et al.'s (2000) prospective study of 81 children in highly dependent units (immobile patients) revealed a similar incidence rate to the current study (7%), yet, the PICU incidence rate in Willock et al. was higher, 15%. However, omitting category *I*; blanchable erythema, from this group would cause the incidence rate to fall to 9.4% (n= 3), which mirrors more closely the rate reported in this thesis.

Several studies of critically ill children have revealed incidence rates similar to Willock et al.'s (Schindler et al., 2007, Fujii et al., 2011, Huffines and Logsdon, 1997, Neidig et al., 1989), although blanchable erythema was not included while categorising ulcers in these studies. Another study of 271 PICU patients revealed a 26% incidence rate of PU. However, this also dropped to only 7% when blanchable and non-blanchable erythema, were excluded (Zollo et al., 1996).

The discrepancy between the incidence rate reported in this thesis and those of other related studies could be explained by:

- Having different definitions for PU categories based on the use of different PU classification systems. For instance, some studies considered redness or blanchable erythema as category *I* ulcers, while others did not. Willock et al. (2000) counted blanchable erythema as category *I*, in line with their use of the Torrance classification system. According to the authors, however, this was thought to inflate the actual incidence rate, which was only 3.6% (n=3) if this category was excluded. For the current incidence study, the EPUAP classification system of PU was used (EPUAP and NPUAP, 2009), excluding category *I* PU (non-blanchable erythema) would result in a 5.2% (n= 11) incidence rate, which is closer to Zollo's (1996) findings (7%, n= 20).

- Using different terminology in describing or while counting PU. For example, certain terms are used interchangeably in some studies, such as referring to skin breakdown as

PU (Zollo et al., 1996), or considering redness as another type of skin breakdown (Schindler et al., 2007), while others consider skin breakdown to be a broader term that covers several skin problems in addition to PU, such as dermatitis, or intravenous extravasations (Noonan et al., 2006). However, the use of standardised terminology in prevalence and incidence studies is thought to be crucial to allow comparability across variant populations and settings (Kottner et al., 2009b). That said, in this incidence study, only cases of PU were investigated, and no other types of skin breakdown were counted.

- Many paediatric PU incidence studies have investigated very specific populations of children, for example, incidence of occipital ulcers in children post open heart surgery (Neidig et al., 1989), or incidence of PU in orthopaedic patients visiting one wound care clinic (Samaniego, 2004).

- Whether there was one, or several, data collectors. This may affect the reliability of the study's findings, since different assessors may vary in the way in which they categorise ulcers. However, the accuracy of ulcers being identified by one rater as opposed to multi-raters is still unclear (Kottner et al., 2009b).

Searching the literature, two studies were identified which surveyed the same population as this incidence study, critically ill children (Curley et al., 2003a, McCord et al., 2004). However, McCord et al.'s study had a different research design (case control), with a smaller sample size (118 patients), and a larger number of studied risk factors. No incidence rate was estimated for their sample, as the goal of the study was to investigate the risk factors in this population. Curley et al. (2003a), on the other hand, used a prospective design, and a larger sample size. Yet, their study excluded neonates and premature babies as well as children over 8 years old, which may affect the generalisability of its results, and the comparability of the size of the problem in other PICU populations, as compared with the current study.

In Curley et al (2003a), 322 patients were recruited from three PICUs, and 86 of these patients were seen to develop 199 PUs, giving an incidence rate of 27%. Adding an extra 27 device-related ulcers would raise the incidence rate even more. Conversely, the

incidence rate in the current research work was only 3.3% (n=7), but increased to 9% (n= 19) when device–related ulcers were included.

The high discrepancy between the two studies might be partly due to the number of assessors involved in each study. As mentioned earlier, having a team of assessors may lead to over- or under-reporting the existence of PU. The discrepancy may also be caused by the nature of the children studied in Curley et al. (2003a), who seemed to represent more complicated cases when compared with the current sample.

All patients in Curley et al.'s (2003a) study had been immobile for at least 24 hours, with 75% being on MV and 21% on paralytic medications, while 76% had received sedative and analgesic medications. For the current study sample, immobility was not among the inclusion criteria, and only 38% of the children and neonates were supported with MV (n= 82), while only 6% received sedative or paralytic medications (n= 13).

Table 5.1: Summary of Possible Causes of Low PU Incidence Rate

Possible Causes of Low Pressure Ulcer Incidence Rate
- Having a single data collector. - Using a different PU classification system, and not including blanchable erythema. - Having a different population and setting for the incidence survey. - Using different terminology or definitions of PU, and skin breakdown. - The Hawthorn effect, by increasing nurses' awareness of PU and preventive measures.

Moreover, the fact that neonates accounted for the vast majority of the sample may have affected the incidence rate. Although young children have been reported as being at a

higher risk of developing PU (Neidig et al., 1989, Curley et al., 2003a, Schindler et al., 2007), especially those of less than one year of age (McCord et al., 2004), no study has reported an increased risk of PU occurrence in the neonatal population as compared with that of other children's age groups. For the possible causes of low incidence rate in this research see (table 5.1).

Compared with previous neonatal PU surveys (Huffines and Logsdon, 1997, Fujii et al., 2011), the mean age of the current neonatal sample was greater (M= 36.3 ± 3.2 (27- 42) vs. 33 ± 3.9 (26-40), and 32.5 (24-41) respectively) and this might have played role in generating a lower PU incidence rate than in the previous surveys. Of the 169 neonates in the NICU, 15 had developed PUs (9%), compared with a 19% (n= 6), and 16% (n=81) incidence rate observed in the NICU in the previous two studies respectively. Premature babies were reported previously to have a higher incidence of PU development, because of their immature skin features (Fujii et al., 2011, Curley et al., 2003a).

Also, the fact that the cases found in the unit at the time of the study were less complicated compared to those of the previous studies, may have played a role in producing a lower incidence rate. Neonates with complicated conditions were mostly excluded from this study either because their condition would not allow the type of positioning which would facilitate the skin assessment, or because they died before any follow-up assessments could be carried out. For example, only one baby boy was established to have been on high frequency ventilation for a diaphragmatic hernia. This baby died before a follow-up assessment was conducted (i.e. he underwent only the initial assessment on admission, assessment= 0).

Moreover, it was noticed that a greater number of preventive interventions were administered in the NICU during this research than in either of the other two units surveyed (the PICU, and GIMU). Although it had not been intended to document any preventive intervention in this work, this could be a reason for the low incidence rate which was found for the NICU sample. Furthermore, in regard to the overall incidence rate, it may be the case that a Hawthorn effect developed while the study was carried out. That is, by increasing nurses' awareness of PU prevention, the study itself may

have actually reduced the incidence of PU. Table 5.2 summarises the main possible causes of the low NICU PU incidence rate.

Table 5.2: Summary of Possible Causes of Low NICU PU Incidence.

Possible Causes of Low NICU Pressure Ulcer Incidence Rate
- The greater mean age of the premature neonates.
- There being less complicated cases, diagnoses or conditions.
- The wide application of preventive interventions.

Although several studies have shown higher incidence rates than this work, there are a few more which represent the other extreme. Two studies, one mail survey (Baldwin, 2002) and the other an incidence audit of one PICU (Murdoch, 2002), reported distinctly lower PU incidence rates: 0.29%, and 0.25% respectively.

Baldwin (Baldwin, 2002) encountered several issues regarding study methods and design. The fact that it was a mail survey, and not a direct skin assessment audit, that it depended on hospitals listed on the web only, and that a low response rate was obtained (only 25% of questionnaires were returned) all affected the reliability of the survey's results, and increased the risk of over- and/ or under- reporting of findings by the accessible hospitals websites, and the nurses' tendency to respond accurately.

Murdoch two incidence studies (Murdoch, 2002) were conducted over a two year period, to compare the size of the PU problem before and after certain type of mattresses were introduced. The investigation covered category *III* ulcers and above, while category *I* ulcers were treated as blanchable erythema. This very low rate compared with other related studies would be higher if category *I* and *II* ulcers had been included.

b) Most Affected Sites

The sites most commonly affected by ulcers in this incidence study were chest and shoulders (20.7%, n=6) and the ulcers observed in these areas were all related to medical devices, such as monitors' cables, ECG leads, and neck collars. Shoulders were

mentioned as a frequent site of PU in one study (McCord et al., 2004)under the category of 'other', and the ulcers in this area were thought to be caused by devices pressing on the skin, friction and shear forces, or incontinence. Curley et al. (2003a) also cite the chest as one of the sites worst affected by category *III* PUs (Curley et al., 2003a).

Occipital ulcers have been found to be one of the most frequent types of PU in children – particularly neonates and young children - in many paediatric studies (Willock et al., 2000, Murdoch, 2002, Neidig et al., 1989, McCord et al., 2004). In this study, only 3 ulcers affected the occiput (10.3%). This may be due to the fact that most of the ulcers found were device-related and were therefore located in areas in direct contact with equipments such as tubes and cables.

According to the main findings of this thesis, further areas badly affected by ulcers were other parts of the head and face; such as the nose and mouth sites (13.8%, n= 4 for each). These types of ulcers have been frequently documented in previous literature (Zollo et al., 1996, Fujii et al., 2011, Curley et al., 2003a). In Curley et al.'s (2003a) study, of the 60 superficial ulcers which were seen to develop, 19 were located on the head (32%). Fujii et al. (2011) noticed that nasal ulcers were the most common type amongst their neonatal population (50%, n=7) and this was thought to be a result of using nasal CPAP machines. Likewise, this would explain nasal PU occurrence in the current study since all nasal ulcers were a consequence of nasal CPAP usage, except for one which resulted from the insertion of a nasogastric tube (NG tube).

One RCT (Yong et al., 2005) which studied all low birth-weight infants admitted to one NICU, reported that nasal injuries linked to the use of a face mask occurred in 12 infants out of 41 (29%), compared to 17 infants out of 48 who developed nasal injuries following the use of a prong (35%). However, the aim of this study was to differentiate between children receiving CPAP by either a face mask or prong, and to measure the associated risks of developing nasal injuries. No intention was made to track the incidence rate of nasal injury; yet, this study did show that nasal trauma would occur when using CPAP through both a nasal prong and facial mask.

Zollo et al. (1996) reported the nose as the most common site of PU in one PICU (28%, n= 33). However, this percentage included other types of skin breakdown as well as ulcers, such as tape burn. In this research, data on tape burn (an adhesive injury) was collected separately and produced an incidence rate of 18.4% (n= 39). If the combined incidence is calculated, the rate would be much higher in this incidence study (27.3%, n= 58) and would be much closer to Zollo et al.'s (26%, n= 71).

Ankle and feet were found to be the second most common sites of PUs along with nose and mouth in the incidence study of this thesis (13.8%, n= 4). These sites were similarly mentioned in previous studies (McCord et al., 2004, Fujii et al., 2011, Samaniego, 2004). The feet were one of the areas worst affected by ulcers following nose in seven NICUs (14%, n= 2) (Fujii et al., 2011). Many studies have also reported heel PUs (Baldwin, 2002, Willock et al., 2000, Murdoch, 2002).

In a retrospective study of 50 orthopaedic patients with PU (Samaniego, 2004), most ulcers recorded had affected the lower extremities of the body, particularly the feet, and they were associated with the use of equipment such as orthoses, casts and wheelchairs. The author highlighted the effect of patients' age on ulceration sites in this population, as sacral ulcers occurred more often as children increased in age. Moreover, most of the children in this sample were aged between 15 and 19 (32%, n= 16). The comparatively old age of the children may have played a role in the fact that more lower ulcers than those which affected the upper extremities or head were found.

In addition to the previously mentioned study (Samaniego, 2004), Baldwin (2002) found that children are like adults in terms of the sites on which their ulcers are found, since most identified ulcers were observed in the areas under the waist, especially on the sacrum or coccyx (40%), and heels (27%). This study, however, had several limitations due to the chosen research design, as mentioned previously.

In the current incidence study, many ulcers were documented under the sub-item 'others'. This category included ulcers which affected the back, buttocks, arms, and ears (17.2%, n= 5). All these were device related; arm ulcers were a result of the friction of cuff pressure on patients' skin, and another was caused by an ID band used on one

neonate. One back and one buttock ulcers resulted from lying on monitor cables, and one ear ulcer was caused by the use of face masks supplying O2.

One study (Zollo et al., 1996) found 16 buttock ulcers among 71 PU-patients in one PICU (13.9%), while another documented some patients with ear and coccyx ulcers (Curley et al., 2003a). Baldwin, in her mail survey (2002), also noticed 40% of under the waist PUs in paediatric patients were located in the sacrum or coccyx.

c) Pressure Ulcer Categories

Most ulcers which were seen were superficial (89.7%, n= 26), as was also the case in previous literature (Willock et al., 2000, Neidig et al., 1989, Zollo et al., 1996, Curley et al., 2000, Fujii et al., 2011, Baldwin, 2002, Samaniego, 2004). In the current study, category *II* PUs were the most prevalent (48.3%, n= 14) followed by category *I* ulcers (41.4%, n= 12), then category *III* (10.3%, n= 3).

Category *II* ulcers were also documented before in previous paediatric incidence studies as being the most prevalent category of identified ulcers. For example, in a study of children who had survived open heart surgery, 50% of detected occipital ulcers were category *II* (n=5), while five others were category *I* in one PICU (Neidig et al., 1989). Another multisite survey of 81 neonates revealed that 68.6% (n=11) were category *II*, followed by 21.4% (n= 3) category *I* ulcers (Fujii et al., 2011). Also, Baldwin's mail survey (2002) showed that category *II* PU were the most commonly occurring type. Samaniego (2004) too, noticed that category *II* ulcers were the most frequently observed in a retrospective study of 50 PU orthopaedic children (74%, n= 37).

The high incidence of superficial PUs in this incidence study might be a result of the fact that most ulcers observed in this sample were device related (63%, n= 12) and most of this type are usually category *I* and *II* (Schluer et al., 2009). Moreover, because children were not assessed on a daily basis, the ulcers might have surfaced on days in which there was no assessment (assessment was done three times weekly in the first two weeks), hence being first observed as category *II*.

On the other hand, a few other studies have identified category *I* ulcers as the most frequently occurring (Curley et al., 2003a, Willock et al., 2000). In Curley et al., category *I* ulcers were the most common (70%, n= 139), followed by category *II* (27%, n= 54), then category *III* (3%, n=6). In Willock et al.'s (2000) study, all of the ulcers identified were either blanchable or non-blanchable erythema (n= 6), and none were classified as more sever categories.

Most PU-patients had a single ulcer (63.2%, n= 12), compared with seven patients with multiple ulcers (36.8%) in the current study. Likewise, previous research has reported single ulcers as the most frequently observed scenario in paediatric PU-patients (Willock et al., 2000, Fujii et al., 2011, Neidig et al., 1989).

d) General Characteristics of the Sample

Of the total 281 patients identified as potential participants for this study, only 212 met the inclusion criteria (75.4%). Most recruited children were in the NICU (79.7%, n= 168), followed by the PICU (19.8% n= 42), and GIMU (0.5%, n= 1). None were recruited from the GICU during the five month long data collection period. These patients were recruited between December 2011 and May 2012.

Most PU incidence studies of paediatric patients were conducted in PICUs (McCord et al., 2004, Schindler et al., 2007, Curley et al., 2003a, Zollo et al., 1996, Murdoch, 2002) and two identified took place in NICUs (Huffines and Logsdon, 1997, Fujii et al., 2011). As in this study, a spotlight on paediatric critical care units was sought because of the increased evidence that their patients are at higher risk of PU formation (Willock and Maylor, 2004, Schmidt et al., 1998, Curley et al., 2000, Zollo et al., 1996, Neidig et al., 1989).

Of the 69 patients excluded from this study of the research, the majority were omitted because they underwent fewer the minimum requirement of two assessments (60.9%, n= 42). For any child who was assessed only once (on admission), it was impossible to track the development of any PU, so they had to be excluded. Moreover, 19 children

failed to give consent (27.3%), while four other children were cared for in isolation units (5.8%) and were excluded because of their higher susceptibility to infection.

Two more children had been admitted to the ICU with home-acquired ulcers, one patient was discovered to be over 18 years old, and another had a severely deteriorated condition especially when repositioned or moved, which made it impossible for the investigator to properly conduct the skin assessment. Children who were in isolation or those with deteriorated conditions when positioned have also been excluded in previous similar paediatric studies (Fujii et al., 2011, McLane et al., 2004).

Of the children included in the final sample, more than half were male (58.5%, n= 124), and all were aged between 3 days and 17 years old, which is partially the same age range covered by previous paediatric incidence studies (Willock et al., 2000, McCord et al., 2004, Baldwin, 2002, Samaniego, 2004, Schindler et al., 2007, Willock et al., 2005a). This age range was targeted so that no children - even preterm babies - would be excluded. However, most of the study sample was composed of neonates (0 - 30 days old) (79.2%, n=168), of which full term babies constituted 46% (n= 97) of the total sample, and preterm babies constituted 37% (n=79). On the other hand, the age group least well represented in the study were preschoolers (children age > 3 years up to five years) (0.9%, n= 2).

In most cases, follow-up assessments were discontinued when the patient was discharged (95.3%, n= 202), or due to the patient's death (4.2%, n= 9). Only one patient underwent the maximum number of assessments; that is, 12 over a two month period. The relatively high number of patients who died during the study might be a reflection of the severity and acuity of their health conditions; yet, none of these patients had developed PU during the follow-up period. This might be related to the fact that their death occurred soon after their admission, before they had a chance to develop PU. The high mortality rate may have played some role in lowering the incidence rate of PU in this sample.

The number of follow-up assessments carried out for each patient in the sample ranged from two consecutive assessments up to the maximum of 12 assessments, including

assessment zero (the initial assessment), with a median of two assessments. The vast majority of the patients had at least two follow-up assessments in addition to the initial assessment (75.5%, n= 160). More specifically, more than half of the children had two assessments (63.2%, n= 134), followed by those who had three (12.3%, n= 26), and four assessments (7.1%, n= 15). Only one child had 12 assessments (0.5%); however, another 4 children underwent more than 9 assessments (1.8%).

Most children in this sample had respiratory problems as the primary medical diagnosis (59.9%, n= 127), followed by metabolic and infectious diseases respectively (11.8%, n= 25; and 10.8%, n= 23). Children admitted with respiratory diagnoses were thought to be at a higher risk of PU occurrence (Schindler et al., 2007), than children who were admitted to the PICU with different conditions (P= 0.008).

5.5.2.2 Risk Factors for PU development

To ease explaining the contributing factors for PU development in this study sample, the discussion was divided under two major headings derived from the statistical analysis: univariate and multivariate. Risk factors based on univariate analyses were then classified under three major sub-headings: general risk factors, Glamorgan sub-items, and Braden Q sub-items. As regards the multivariate heading, risk factors were discussed with reference to four major models: the Braden Q sub-items, the Glamorgan sub-items, the Braden Q sub-items with general risk factors / predictors, and the Glamorgan sub-items with general risk factors / predictors. This was done for easier identification and follow-up of the main findings. See diagram 5.2 below:

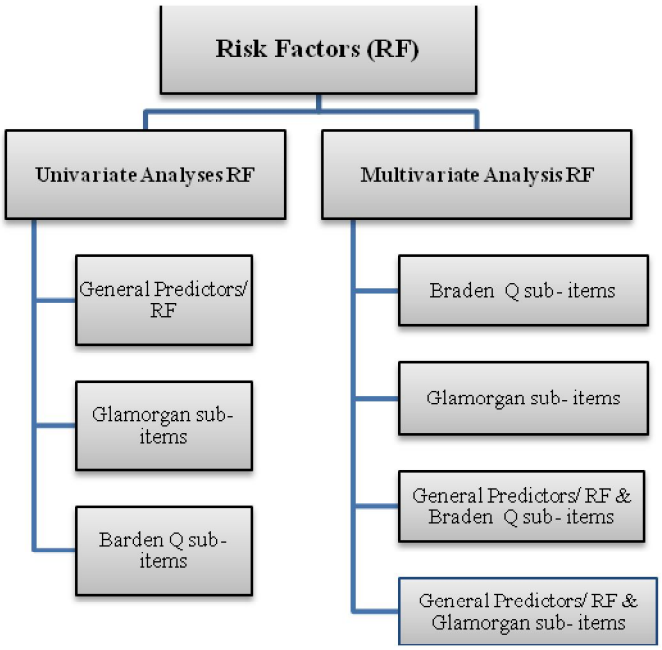

Figure 5.2: Summary of Risk Factor Classifications

a) Risk Factors based on Univariate Analyses

The use of univariate analyses revealed 17 significant risk factors for PU development among Jordanian children receiving care in ICUs. Using the *Chi Square* (χ^2) test and *Fisher's Exact* test for categorical variables, and the *Mann Whitney U* test and the *independent samples t- test* for continuous variables, with a significance level of < 0.05, the following risk factors were highlighted: 'being on MV', 'duration spent on MV', 'age in days' (age < 1 year old), 'ICU LOS', 'GCS score', and 'PEEP level'.

Furthermore, three sub-items of the Glamorgan RAS - *mobility*, *equipment pressing on skin*, and *nutrition*, - as well as the Glamorgan total risk classifications. Moreover, six sub-items of the Braden Q RAS were significant - *mobility*, *activity*, *moisture*, *friction and shear*, *sensory perception*, *tissue perfusion and oxygenation* - in addition to the Braden Q total risk score classifications.

Each of these factors is discussed separately in the following sections;

i) General Risk Factors / Predictors

This group of risk factors includes predictors of PU which were identified using univariate analyses. It contains general factors that are related to the PU patients' characteristics, laboratory tests, or their stay in the unit, and that were collected initially based on the related previous literature. The factors are 'being on MV', 'use of PEEP', 'age in days', 'GCS score', 'ICU LOS', and 'duration spent on MV', and all are discussed below, except the last variable which is discussed later in the multivariate analysis section.

- ***Being on Mechanical Ventilation***

This variable was found to be significantly related to PU development in this population (χ^2*= 20.4; d.f. = 1; p<0.001*). Patients who developed PU were found to be supported on mechanical ventilation more often than those who remained PU-free, since 89.5% of PU patients were on MV (n= 17), compared with 33.7% of the PU-free patients (n=65).

This finding was supported by several previous studies. Zollo et al. (1996), for example, reported 59 patients out of 65 with impaired skin integrity were supported on MV, compared with 50 out of another 65 PU-free patients. MV was also found to be a significant risk factor for PU development in 322 children aged from 21 days up to 8 years in three PICUs (Curley et al., 2003a), where mechanically ventilated patients were found to be eight times more at risk to develop PU than patients who were not supported with MV, this result based on both univariate and multivariate analyses (*OR= 7.84, 95% CI, 3.05-20.1, P<0.001*).

Schindler et al. (2007) also found that mechanically ventilated paediatric patients had a higher risk of developing skin breakdown and redness than PU-free patients (*P< 0.001*), yet this difference failed to prove significant based on a multivariate analysis (*OR=1.71; 95% CI, 0.82-3.56, P=0.16*). patients supported with specific types of MV, such as HFOV, were also noticed in Curley et al. (2003a) to be at seven time more risk to develop PU than patients not supported with such type of ventilation (*OR= 7.32, 95%CI, 2.23-24.1, P= 0.001*).

Furthermore, other studies have reported intubation as a risk factor, rather than mention MV specifically. One multisite neonatal incidence study (Fujii et al., 2011) reported endotracheal intubation as one of two highly significant risk factors for PU development in this population (OR= 4; 95% CI, 1.04- 15.4, P= 0.042). MV was proved significant by both univariate and *stepwise LR*. Another case control study (McCord et al., 2004) which examined over 118 children in one 30-bed ICU, found that intubated children had a higher risk of developing PU (P=0.002), although this factor was not significant with the significance level set to < 0.002.

The effects of MV or of the intubation itself on children's susceptibility to PU development are believed to be different. Ventilated patients are usually sedated and have poor perception so they cannot communicate any sense of pressure or discomfort, which might increase their risk for PU (Curley et al., 2003a). On the other hand, intubation affects the number of times the children would be repositioned, which increases the magnitude and duration of pressure on their skin, resulting in PU development. Furthermore, intubated children, and particularly neonates, would usually be supported on nasal CPAP, which is thought to increase nose compression necrosis and nasal deformities (Fujii et al., 2011).

The way intubation affects children's risk of PU seems to be different than that of MV itself, since MV indicates the patients' difficult respiration, oxygen saturation and hypoxia level, but intubation may increase the compression on patient's skin by the used tracheostomy or endotracheal tube, also, for this study, there was no significant difference between the PU- and PU-free patients in relation to hypoxia.

- ***Positive End Expiratory Pressure (PEEP level)***

Positive end expiratory pressure (PEEP) is revealed to be significantly related to PU development in this study of ICU patients (*U= 361.5, Z_{score}= -1.989, P= 0.047*). PEEP had been previously identified as a risk factor for PU development in one 30 bed PICU case control study, where a high PEEP level was noticed to be closely correlated with PU development (P= 0.002). However, the opposite was observed in this thesis. That is,

PU patients were seen to have lower PEEP levels compared with those delivered to the PU-free patients (Median (IQR) = 5(5.5) vs. 9.7(5)).

McCord et al. (2004) suggest that high PEEP increases children's risk of PU, because of its indirect effect on reducing the frequency of positioning. That is, a high PEEP level is usually applied to children with complicated cases, for whom nurses prefer to limit positioning to avoid further deterioration.

However, the low level of PEEP observed in this research could be related to the high number of neonates in the sample, since most mechanically ventilated PU patients were neonates (73.6%, n=14 out of 19 PU-patients), and 64% of them were on a low PEEP level (n= 9). Low PEEP settings of 3-5 cm H2O were recommended as the basic ventilator setting that neonates should receive when MV is initiated, while older children or those with more complicated cases were recommended to have higher PEEP levels (Khilnani, 2011, Jaypee Brothers, 2006).

Thus, the default low PEEP level was the most common in this paediatric sample. Moreover, a low PEEP of 3-4 cm H2O has been described as the physiologic level in which children without muscle relaxant need to receive (Khilnani, 2011). That is also applied to this sample, in which the vast majority of mechanically ventilated children were not on sedative or paralytic medications.

- ***Age in Days (less than one year old):***

Infants (children under one year old) were the most affected with PU other than older groups of children (78.9%, n=15). An age of less than one year old was found to be significantly related to PU development based on the univariate analysis (U= 595, $z_{score} = -3.527$; $P < 0.001$), as in many previous paediatric studies (Neidig et al., 1989, Zollo et al., 1996, Curley et al., 2003a, Huffines and Logsdon, 1997, Baldwin, 2002, Schindler et al., 2007, Suddaby et al., 2005).

Critically ill children who are one year old or younger was reported to have the highest risk of PU development of all age groups of children (*OR= 1.27; 95% CI 1.02-1.57; P= 0.03*) (Curley et al., 2003a). Moreover, those who are under two years old have been

reported to have double the risk of developing PU compared to older children, based on multivariate analysis (*OR= 2.57;95%CI 1.39-4.47; P= 0.002*) (Schindler et al., 2007). One more study (Zollo et al., 1996) found, through univariate analysis, that age is significantly related to skin breakdown in PICU, although this failed to show significance based on multivariate analysis.

Children under 3 years old have been noted to have a higher incidence of PU occurrence than older children in many different populations, such as medical-surgical ward patients (Suddaby et al., 2005), cardiac patients following open heart surgery (Neidig et al., 1989), and general ward patients (McCord et al., 2004), also, in the previously mentioned McCord et al' study, 36% of PUs occurred in children aged one year and younger (n= 21).

A few other studies have mentioned young age as a typical characteristic of children who develop PU even though they did not explicitly study age as a risk factor (Willock et al., 2000, Baldwin, 2002, Suddaby et al., 2005). For example, Baldwin (2002), found that children under 10 years old accounted for 47% of the total number of ulcers identified, yet, this descriptive data related to a mixed incidence and prevalence mail survey. Also, Suddaby et al.'s (2005) study, as previously mentioned, had a questionable cross-sectional research design, making it difficult to infer any relation between young age and the occurrence of skin breakdown.

Willock et al. (2000) have also reported that PU-patients were infants and young age children, specifically those with occipital PU. However, Samaniego's (2004) findings contrasted with those previously discussed as, in this study, teenagers (15-19 yrs) were the age group most affected by PU (32%, n=16). However, this could be a unique result for this specific orthopaedic population.

- ***Glasgow Coma Scale Score (GCS)***

The GCS is an indicator of patients' level of consciousness, established by assessing their eye opening response, as well as their verbal and motor abilities in responding to

an external stimulus (Holmes et al., 2008). A low GCS score indicates a lower level of consciousness and higher possibility of brain injury.

Patients who have a diminished level of consciousness might be unable to sensate pressure or pain, so they would be unable to change position accordingly, and this may increase their risk of developing PU (Willock et al., 2000, Willock et al., 2005b). Moreover, patients with low GCS scores are usually patients who are sedated, on MV, or those who have serious head injuries which would also increase their risk of responding poorly to pressure, and hence of PU occurrence (Willock et al., 2000).

For the current study, GCS appeared to have a significant correlation with PU development (U= 712.5, Z score= -4.61, P < 0.001). PU patients showed lower GCS scores compared with PU-free patients (Mean± SD= 9.5± 3.8, Median (IQR) = 11(1) vs. Mean= 10.9± 3.3, median= 14(3)). This finding indicates that patients who developed PU later in the study were less conscious and oriented compared with the more conscious PU-free patients. Only one previous study (Willock et al., 2000) has reported low consciousness level as a characteristic of 11 PU- paediatric patients out of 18 children with PU (72%), yet it was a descriptive mixed incidence and prevalence study.

Despite the paucity of paediatric literature which describes GCS as a risk factor for PU development, it could be implicitly combined with many other factors that are well documented in previous literature as PU risk factors, such as sedation application, and MV usage (Curley et al., 2003a, Neidig et al., 1989). These measures would necessitate reducing patients' consciousness level, to relieve discomfort and counter resistance to intubation. One study (Dixon and Ratliff, 2005) also identified children who were more prone to ulcers to be those who received sedation, were on MV, immobile, hypotensive and critically ill. However, these descriptive data were based on a cross-sectional prevalence study.

The PRISM score (Paediatric Risk of Mortality Score) has also been named as one of the risk factors for PU and skin breakdown occurrence in paediatrics (Zollo et al., 1996, Schindler et al., 2007). It incorporates several indicators of patients' physiological

health assessed within the first 24 hours of admission to PICU, and GCS is one of these indicators (Butler, 2007).

Furthermore, achieving higher scores through the use of specific scales to measure paediatric patients' neurological response was found to be associated with PU occurrence in ICU patients (Zollo et al., 1996, Curley et al., 2003a). Zollo et al. (1996) found that children who achieved higher POPC scores were most affected with skin injuries, as Curley et al. (2003a) who found that scoring high by Ramsay scale was associated with higher risk of category *II* and above PUs. For these both mentioned scales, higher scores mean poorer neurological response.

On the other hand, many paediatric RASs have a specific category to measure patients' levels of perception, sensation and consciousness (Bedi, 1993, Quigley and Curley, 1996, Cockett, 1998, Barnes, 2004), and these are strongly linked with patients' GCS scores. For example; in the Braden Q RAS, which has appeared as a significant indicator of PU development in paediatrics (Schluer et al., 2009, Curley et al., 2003a), one of the sub-items is concerned with measuring sensory perception. According to the authors, this could be based on measuring consciousness and/or measuring sensation through the GCS or measuring sedation level using the State Behavioural Scale (Noonan et al., 2011). However, risk scales and their sub-items are discussed later in this chapter as distinct risk factors.

- ***ICU Length of Stay (LOS)***

Patients' LOS (in days) in ICUs in this research have been shown to be significantly related to PU occurrence ($U= 437$, Z score= -5.57, $P<0.001$). With a range from 3 days up to 56 days, patients who developed PU spent significantly longer periods of time in ICU compared with those who remained free of ulcers (median (IQR) = 13(13) vs. 5 (5) respectively). However, this is often controversial, since it is not absolutely clear whether the high LOS increased the risk of PU, or if having PU increased the need to stay in hospital / ICU for lengthy periods.

A lengthy stay in ICU has already been reported as a factor which contributes to PU development. Neidig et al. (1989) noted that children who survived open heart surgery and who stayed in PICU for longer than eight days had a higher incidence of occipital PU occurrence (χ^2*= 9.83, d.f. = 2, P= 0.007*). Although the mean length of stay in the ICU for the current sample was longer than in Neidig et al.'s study, the range difference between PU patients and PU-free patients was almost the same ((19.5±15.3 vs. 11.2±10.7) and (12.9±12.6 vs. 4.9±5.2) respectively). On the other hand, Zollo et al. (1996) noted a lower mean length of stay for skin breakdown patients than that observed in the sample investigated for this thesis (9.75±12.7 vs. 19.5±15.3).

On the other hand, it has been observed elsewhere that shorter LOS is more closely correlated with PU occurrence. For example, this was the case in McCord et al.'s case control study (2004), where an ICU LOS as low as four days was attributed to the higher incidence of PU in this population (P= 0.001). Using univariate and multivariate analyses, Schindler et al. (2007) revealed the same length of stay risk period (4 days) in patients with impaired skin integrity (OR= 1.17; 95% CI 1.09-1.25; P <0.001).

Lengthy periods in PICU have also been previously discussed as a contributing factor for PU formation, because it is thought to be connected with having limited mobility and fewer positioning times (McCord et al., 2004, Neidig et al., 1989). Sometimes, it was also highlighted as an indication of the time the patients had spent being intubated (Neidig et al., 1989). In addition, this factor may be interrelated with other risk factors, such as suffering from poor nutrition and weight loss (McCord et al., 2004).

ii) Risk Factors (based on the Glamorgan RAS)

According to the univariate analyses, only three sub-items of the Glamorgan RAS were significantly related to PU development among the critically ill children. These are: *mobility* (*U= 1125, Z score= -3.428, P< 0.001*), *existence of pressing equipments* (χ^2*= 11.94, d.f= 1, P= 0.001*), and *nutrition* (χ^2*= 4.28, d.f= 1, P= 0.038*), in addition to the Glamorgan total risk classifications: 'no risk', 'risk', 'high risk', and 'very high risk' (Fisher's= *19.73, d.f= 3, P< 0.001*). PU-patients were identified as having restricted

mobility (63%, n= 12), had a poorer nutritional condition (94.7%, n= 18), and all had medical equipment pressing or surfaces rubbing against their skin (n= 19).

- ***Restricted Mobility***

Around 63% of all patients who developed PU in this incidence study had different levels of immobility, which was assessed using the Glamorgan scale (n= 12). Based on Glamorgan, 21% of PU-patients (n=4) suffered 'great difficulty' in positioning and mobilisation, while seven patients had 'some limitation' in mobility that affected their developmentally-appropriate physical movement, and an equal number had 'normal mobility' for their age (36.9% for each category). Only one patient 'needed assistance' in mobilising and positioning (5.3%).

For this sub-item of the Glamorgan scale, any problem affecting child mobility, physical activity, or positioning feasibility was counted as a risk indicator for PU occurrence (See Appendix 1.8 for terminology of the Glamorgan RAS items).

Although almost all paediatric RASs have limited mobility as one of their risk categories (Garvin, 1997, Cockett, 1998, Willock et al., 2007, Quigley and Curley, 1996, Bedi, 1993, Pickersgill, 1997, Huffines and Logsdon, 1997, Suddaby et al., 2005, Olding and Patterson, 1998a, Barnes, 2004, Waterlow, 1998), the meaning of this term varies widely. The Braden Q scale differentiates between *mobility*, which is defined as the child's ability to change position, or to move in bed, and *activity level*, which is defined as the child's ability to ambulate based on their developmental levels (Noonan et al., 2011, Quigley and Curley, 1996). (See Appendix 1.9 for terminology of the Braden Q RAS items).

The neonatal skin risk assessment tool NSRAS (Huffines and Logsdon, 1997), and the modified neonatal / infant Braden Q RAS (McLane et al., 2004), were both developed based on the original Braden Q RAS, and hence shared the same definitions of *mobility* and *activity* sub-items, while at the same time took the different developmental levels of children into consideration. The mobility sub-item in the NSRAS (Huffines and Logsdon, 1997), however, was omitted from the inter-rater reliability pilot study of the

tool, because of its poor reliability score between different ratings and different assessment days of 32 NICU' patients.

Another newly developed scale, the Braden Q+P risk scale (Galvin and Curley, 2012), based on the Braden Q, is used to predict surgical patients' risk of developing ulcers, before, during and after their operations. In this, *activity level* has been omitted since all children in the operation room (OR) would be sedated. Also, the *mobility* sub-item is measured according to the length of the surgery rather than by the child's ability to change position. How frequently the OR nurse changes the child's position is also documented.

Other paediatric scales do not distinguish the patient's ability to control body position from that of being able to ambulate. Most refer to mobility as the ability to change position and walk in varying degrees, according to the child's condition, such as being restless or in need of assistance (Bedi, 1993, Cockett, 1998, Garvin, 1997, Pickersgill, 1997, Olding and Patterson, 1998a). However, the mobility and activity categories should be able to distinguish risk between the different and varied age groups of children and infants, based on their developmental levels (Willock et al., 2000)

Waterlow (1998) did not mention mobility explicitly in her paediatric version of the Waterlow assessment tool; rather, a question related to the child's physical abilities was formulated. However, she did mention that any immobile child with a mix of other risk factors would be much more susceptible to developing PU.

Children with restricted mobility have been previously said to have a higher risk of developing PU and skin breakdown (Willock et al., 2000, Huffines and Logsdon, 1997, Samaniego, 2004), and further studies have highlighted several risk factors that are interrelated with patients' mobility, such as taking paralytic and sedative medications (Curley et al., 2003a, Zollo et al., 1996, McCord et al., 2004), being intubated or on MV (Neidig et al., 1989, McCord et al., 2004, Curley et al., 2003a, Fujii et al., 2011, Schindler et al., 2007), the need for positioning / infrequent positioning or using special beds for turning (McCord et al., 2004, Fujii et al., 2011).

These factors are different from mobility itself, but have been noted to affect patients' mobility and activity. Patients on sedation or who are mechanically ventilated are unable to independently change their positions, or to move their body spontaneously on feeling pressure or pain. Being unable to respond to prolonged pressure or intense friction and shear forces, decreases the skin's tolerance of these forces, which results in compression on patients' skin, ischemia, and necrosis (Neidig et al., 1989).

Murdoch (2002), reported the case of a 10 year old child who was admitted to hospital with several spine fractures following an RTA. Because of the child's delicate condition, cardiac instability, and multiple fractures, he had been confined to a spinal board for more than 36 hours. The child had developed category *III* and *IV* ulcers on both the occiput and sacrum. According to Murdoch's experience, any child who is not fully well or immobile is at risk of developing PU, and so requires special care.

One incidence and prevalence study (Willock et al., 2000) found that most PU-patients identified had impaired mobility (89%, n= 16). This was thought to decrease patients' ability to turn or to change position when feeling pressure or pain. Another multi-site study (Willock et al., 2005b) of 54 PU-patients reported that the majority had limited mobility, and more than half were completely immobile. However, no statistical significance of this feature was achieved.

One more retrospective chart audit of 50 patients who had PUs (Samaniego, 2004), which took place in a hospital wound clinic, found that immobility is a risk factor for PU development among orthopaedic patients. Around 14.6% of PU-patients (n=8) had Myelodysplasia as the primary diagnosis. The mobility predictor, based on the Braden RAS, gave the lowest scores for this particular population and lower scores, according to this scale, indicate a higher risk of PU development (Mean ± SD= 2.3 ± 0.74).

- ***Impaired Nutrition***

All except one of the PU-patients in the current research complained of impaired nutrition, as assessed according to the Glamorgan RAS (94.7%, n= 18), yet a high percentage of PU-free patients did so as well (69.4%, n=134). Thus, based on this

Glamorgan sub-score, around three quarter the whole sample had suffered some sort of nutritional problems (72%, n= 152). Impaired nutrition has also been noticed to be a feature of PU-paediatric patients in previous studies (Huffines and Logsdon, 1997, Willock et al., 2000, McCord et al., 2004, Murdoch, 2002).

In the current study, nutrition was scored according to the initial condition of the patient on admission, even though it has been established elsewhere that it is best to score this item over time (Curley et al., 2003a). Another reliability study (Huffines and Logsdon, 1997) found that the best inter-rater reliability coefficient of *nutrition* sub-score was on the third day after the birth of neonates (*r= 0.99*), and the worst was on the first day (*r= 0.77*). However, in the univariate analysis, no significant difference was detected between these different scores across seven follow-up days.

Therefore, the initial assessment was used to estimate children's risk of PU in this study, because the researcher was eager to make a decision about this sub-item's ability to predict patients' risk in the early stages of their admission. Also, the high turnover rate of patients admitted to the ICUs make it difficult to follow this item in these patients for longer periods, since most of the sampled patients had ICU LOS less than three days. However, assessing the nutritional condition of patients on the admission day may account for the high percentage of PU-free patients who scored risk based on this sub-item.

Impaired nutrition was one of the three most reliable indicators of skin breakdown in a neonatal population in research by Huffines and Logsdon (Huffines and Logsdon, 1997), and in Willock et al. (2000), 16 out of 18 PU-patients were on diets that were considered inappropriate for their age (89%). However, Willock et al.'s findings were extracted from a descriptive data of a small sample, while Huffines and Logsdon' study was a pilot study conducted on a small sample of 32 neonates.

Moreover, based on a significance level of ≤ 0.05, the absence of nutrition was established as a significant predictor of PU in critically ill children in one 30 bed PICU (*P= 0.04*) (McCord et al., 2004). Ultimately, however, this item was omitted from the study's list of significant risk factors, since the authors considered only factors that had

a significance level of < 0.002 as predictors of PU, in an attempt to decrease the effect of *type I* error.

Usually, most children admitted to critical care units would be NPO (Nothing per Oss) at least at one point during their stay and even when feeding was initiated, there would be a risk of it being ceased if signs of intolerance were observed. Also, food would be given slowly most of the time, which could affect whether the children received adequate nutrition (McCord et al., 2004).

Patients who are malnourished or have imbalanced diets are thought to be at risk of weight loss which, in turn, increases bone prominence, which increases the patients' risk of developing PU in particular areas (McCord et al., 2004). In addition, critically ill children are at increased risk of inadequate nutrition and hence PU formation, because of their high expenditure of calories, and sometimes the catabolic nature of their diseases (Murdoch, 2002).

- ***Existence of Equipment***

In this thesis, all identified PU-patients were supported by medical devices (100%, n= 19), compared with only 56.5% of PU-free patients (n= 109). Twenty ulcers out of 29 were equipment-related ulcers (69%). Of these, the most prevalent type were ulcers caused by ECG leads (25%, n= 5), followed by the endotracheal tube (20%, n= 4), and nasal CPAP / tube (15%, n= 3). Several other types of medical devices were found to cause ulceration in this sample, including ID bands, cuff pressure, cables, O2 probes, NG tubes, face masks, and neck collars.

The following types of medical equipment have been established previously as contributing factors for PU development: endotracheal intubation / CPAP / ECMO/ HFOV (Fujii et al., 2011, Yong et al., 2005, Gershan and Esterly, 1993), tubes and syringe caps (McCord et al., 2004, Murdoch, 2002, Schluer et al., 2009, Noonan et al., 2006), O2 probes (Curley et al., 2003a, Murdoch, 2002, Noonan et al., 2006), and electrocardiogram leads (Murdoch, 2002).

Ulceration related to equipment usage has been documented repeatedly in paediatric literature, especially among those who are critically ill (Curley et al., 2003a, Willock et al., 2005b, Waterlow, 1997), and in orthopaedic patients (Samaniego, 2004). Most of these types of ulcers are located in unspecified areas on the body. For example, according to McCord et al. (2004), the face, chin, feet and shoulders were the most frequently observed PU-affected areas in PICU patients as a result of either the use of medical devices, incontinence, or friction and shear forces. In the current research, the large number of device-related ulcers might explain the high incidence of ulcers in unspecified body sites, labelled 'others'.

In one study, 27 device- related ulcers were caused mostly by SpO2 probes (n= 14), in addition to others resulting from the use of CPAP masks, casts and tracheotomies (Curley et al., 2003a). Another study of orthopaedic patients highlighted several external factors as being associated with PU development, including casts, orthoses, and wheelchairs (Samaniego, 2004). Such medical equipments have also been discussed in other previous studies (Willock et al., 2005b, Schluer et al., 2009, Waterlow, 1997). Willock et al. (2005b) reported that more than half of the PU patients (n= 24) identified in their incidence study, had PUs associated with devices.

Suddaby et al. (2005) noted the significance of this risk factor among PICU, adolescent, medical-surgical, and oncology patients, finding that those supported by a variety of medical devices were at a 46% higher risk of developing skin breakdown than patients who were free of or had fewer devices involved in their care (OR= 1.46%, 95% CI 1.69, $P \leq 0.05$).

Although some of these findings could be more closely related to one group of children over other, critically ill children in general would usually require most of these equipments to be used during their admission to the ICU. For example, immobile children would need the use of a wheelchair even if they did not suffer from orthopaedic problems. Also, splints are usually applied to ICU patients to protect the infusion lines or as corrective casts (Waterlow, 1997).

- ***Glamorgan Total Risk Score Classification***

The risk classification of the Glamorgan sum score was highlighted as significantly related to PU formation among Jordanian critically ill children (*Fisher's= 19.73, d.f. = 3, P <0.001*). Even though this scale was able to correctly identify all PU patients (n=19), it was unable to correctly identify 119 out of 139 of the PU-free children (61.7%), which means that this scale was highly sensitive but less specific for this population. However, this thesis did not aim to control nursing interventions targeted at preventing ulcers, which might have caused the low specificity of the scale since proper prevention protocols are thought to prevent actual PU occurrence, even if the child is at actual risk.

iii) Risk Factors (based on the Braden Q RAS)

This section covers predictors of PU found as a result of using the Braden Q RAS. According to univariate analyses, six out of seven Braden Q sub-items significantly contribute to PU formation among critically ill patients. These are, *mobility, activity, sensory perception, moisture, friction and shear,* as well as *oxygenation and tissue perfusion,* in addition to the Braden Q total risk classifications. *Nutrition* was the only sub-item which did not appear to be significant.

- **Mobility**

Mobility was closely correlated to PU development in this population (U= 1098, Z score= -3.512, P <0.001). Most PU-patients had some degree of 'restricted mobility' (63.1%, n= 12), with four patients 'completely immobile' (21%). On the other hand, less than a third of PU-free patients had mobility problems (28.5%, n= 55), while 71.5% had 'no mobility limitations' (138). *Mobility* was discussed as a risk factor for PU in critically ill children and neonates in the previous section (risk factors based on the Glamorgan RAS).

- **Activity**

In the current study, around 32% of PU-patients were 'bedridden' (n= 6) and 53% had severe 'difficulty walking' independently (n= 10). While 16% had the ability to 'walk occasionally' (n= 3), none of the PU-patients had a completely 'normal activity' level. By contrast, 57% of PU-free patients had a normal activity level for their age (n= 110). *Activity* was strongly linked to PU development in critically ill paediatrics in this study (*U= 785, Z score= -4.471, P<0.001*).

Compared with the *mobility* sub-item, *activity* seemed to be a more reliable predictor, since *mobility* was only able to identify 60% of patients who developed PU to be at risk, while 40% of those who were classified as not at risk did actually develop PU. On the other hand, all patients who suffered activity problems did go on to develop PU; none of the PU patients were categorised initially as normally active.

This could play a role in explaining the better performance of the Glamorgan *immobility* sub-scores compared with the Braden Q *mobility* sub-scores in the *LR* models, and indicate that a sub–item which combines mobility and activity issues is better than using two different sub-items.

Such an assumption could be explained by the easier identification and scoring of these two items by nurses. If they were combined as one sub-score, it would make it easier to understand each sub-item by reducing confusion about their inter-related terms, and facilitate identification of this risk factor. This would need further work before it could be approved, however, especially since both the *mobility* and *activity* sub-scores of the Braden Q showed no significant relationship with PU development in the multivariate analysis. Nevertheless, using the ROC, *activity* was more predictive of the PU risk than the *mobility* sub-score.

Although the Braden Q scale differentiates between *activity* (patient's physical ability to move and walk) and *mobility* (patient's own ability to change his/her body positioning) risk scores, most previous studies do not. One study, however, has discussed 'high activity' as a risk factor for PU development among orthopaedic patients. High activity

was thought to increase patients' friction with surfaces like beds, as a result of vigorous movement, which might increase their chance of developing ulcers (Samaniego, 2004).

As can be seen, that the definition of 'activity' according to the Braden Q scale is different from Samaniego's study (2004). The latter connects activity to the patient's movement in their bed while Braden Q defines this type of movement as an indicator of mobility rather than activity.

In one neonatal pilot study (Huffines and Logsdon, 1997) which was conducted to test the reliability and validity of a RAS, it was found that *nutrition, activity,* and *general physical condition* had the highest sensitivity and specificity in predicting skin breakdown in neonates. Inter-rater reliability coefficients for the *activity* sub-item ranged between 0.80 and 1.00 over a 21 day study period, which would indicate that *activity* is a reliable predictor of skin breakdown formation within the first 21 days of neonates' lives; however, larger study with variant age groups is needed to confirm this finding.

- **Sensory Perception**

Patients' ability to respond appropriately to pressure or pain stimuli was clearly related to the formation of PU in this sample (*U= 808.5, Z score= -4.27, P<0.001*). All PU-patients had complained of a 'diminished level' of sensation and / or consciousness (n=19), and the majority of cases had 'very limited' perception (36.8%, n= 7).

Sensory perception as a general risk factor has been addressed in previous literature (Samaniego, 2004, Pallija et al., 1999, Bar-On et al., 2002, Willock et al., 2005b, Barnes, 2004). However, as mentioned earlier in the GCS score section, sensation or consciousness level is interrelated with many other PU risk factors, such as using MV, sedation, and being intubated, so these cannot always be discussed separately.

- **Moisture**

Sixteen out of 19 PU-patients had moist skin (84.2%), versus three PU-patients who had 'rarely moist' skin (15.8%). For the current study, the degree of skin moisture (resulting

from drainage, vomit, incontinence, or other) was established to be significantly related to PU development (U= 829.5, Z score= -4.649, P<0.001).

Moisture has been identified as a significant risk factor for skin breakdown and PU development in prior research. Willock et al. (2000) identified dehydration as a characteristic of PU patients (17%, n= 3), while dry or clammy skin were also observed in around 50% of PU cases among children and neonates (n= 9). Nevertheless, the small sample size and the descriptive nature of findings meant that researchers were not able to infer any statistical significance for this factor in relation to the development of PU.

Suddaby et al. (2005) reported frequent episodes of diarrhoea to be one of the risk factors for skin breakdown among children admitted to one medical-surgical unit, yet this was usually associated with diaper dermatitis rather than pressure related injuries. Murdoch (2002) has explained how excessive moisture from urine and faecal incontinence would lead to changes in the skin pH level (normally around 5.5), which may cause alteration in skin integrity and breakdown.

Another term related to moisture and usually considered a risk factor for PU formation in children is incontinence. Through the use of univariate analysis, this has been shown to be (Willock et al., 2007) to be a significant predictor of PU development in children and neonates (P= 0.003). No further studies were identified that proved the same findings in paediatrics. Though Willock et al. have used lower significance level (p<0.01), the retrospective nature of the study might limit its findings. Moreover, no further studies were identified that approved the same findings in paediatrics.

Although *moisture* constitutes a sub-score of many PU risk scales (McLane et al., 2004, Garvin, 1997, Quigley and Curley, 1996, Huffines and Logsdon, 1997, Suddaby et al., 2005, Barnes, 2004), and incontinence appears in others (Willock et al., 2007, Cockett, 1998, Bedi, 1993, Pickersgill, 1997, Olding and Patterson, 1998a), some previous studies have shown neither to be significantly related with PU (Curley et al., 2003b, Anthony et al., 2010).

In Anthony et al.'s (2010) retrospective study, which was developed to compare the predictive capabilities of three paediatric RASs, *moisture* failed to show significance in both the Garvin and the Braden Q scales, as did incontinence in the Glamorgan scale. Curley et al. (2003b) investigated the predictive validity of the Braden Q scale, and found that *moisture*, in addition to another four sub-items of the scale, were not predictive of PU risk in ICU' patients, with an AUC <0.60 (p= 0.08).

- **Friction and Shear Forces**

This sub-item of the Braden Q scale was revealed to be significantly related to PU formation for the population studied in this thesis (U= 927.5, Z score= -3.657, P<0.001). The vast majority of PU-patients had some degree of friction and / or shear problems (94.7%, n= 18), compared to only one patient who did not (5.3%), and developed PU during the follow-up period.

Such forces were mainly observed in neonates in this study since neonates, and patients, who had a deteriorated level of consciousness, were mostly agitated, or slid frequently in their beds. This increased the risk of friction being created between patients' skin and the bed surface, and at the same time increased the shearing forces between the immobile or sedated patients' bodies and bed surfaces and linen as they were being lifted and positioned by nurses, as was often required.

Continuous vigorous movements of children have been reported previously as one of the factors which cause PU (Samaniego, 2004) because of the increased shearing and friction with surrounding surfaces, such as those of beds and supportive casts. According to Samaniego (2004), children who had casts, orthoses or prosthesis had the lowest friction scores, indicating the highest risk of PU, based on the adult Braden scale (Mean± SD= 1.0± 0.25).

Neidig et al. (1989) reported how children became agitated after being extubated from MV following open heart surgery. These patients' vigorous head movements would increase the shearing and friction forces to this area, resulting in increased occipital PU occurrence. In addition, restraints would often be used on these children to prevent self-

extubation, and falling from the bed while being weaned off sedation. The sites where these were applied may also have suffered increased friction and shear. Children in pain are also at risk of friction and shear forces, because unrelieved pain may increase restlessness and agitation in bed (Murdoch, 2002).

- **Oxygenation and Tissue Perfusion**

Around 79% of the PU-patients in this sample had 'compromised' oxygenation and perfusion indicators (n= 15), two more had 'adequate' indicators (10.5%), while another two had 'no problem' in this category of the Braden Q scale. The indicators of *oxygenation and tissue perfusion* such as blood pressure, capillary refill, haemoglobin level, and ABGs, were found to be significantly related to PU development among the ICU' patients (U= 1246, Z score= -2.531, P= 0.01).

This category, or some of its indicators, has also been discussed in previous literature, According to Curley et al. in their incidence study (2003a), children with mean arterial pressure (MAP) of 50 mmhg or less had double the risk of developing PU than the children for whom MAP was greater than 50 mmhg (OR= 2.1, 95% CI 1.1-4.0, P= 0.028).

Patients who are haemodynamically unstable have been established in the literature to have a higher incidence of developing PU than other children and neonates (Willock et al., 2000, Murdoch, 2002, Gershan and Esterly, 1993). Also, when child is haemodynamically unstable, positioning is not a priority for nurses, which may increase their risk for PU occurrence further (Neidig et al., 1989).

- **The Braden Q Total Risk Score Classifications**

The classifications of patients' risk groups based on the total score of the Braden Q were revealed to have a significant association with the occurrence of PU in this study's sample of critically ill children and neonates (*Continuity Correction= 10.51, d.f = 1, P =0.003*). However, the scale was not able to predict around 53% of patients who developed PU to be at risk (n=10), so it had low sensitivity. Yet, it was highly specific

in distinguishing children who classified as not at risk of PU, and who did not go on to develop ulcers (83%, n= 161).

The failure of the Braden Q total risk score to correctly classify patients who develop PU as being at risk was observed before (Noonan et al., 2006), where, the Braden Q classified 6% of children to be at risk of PU, although only 1.6% (n= 4) actually developed PU, and none of these were classified as at risk by the scale. However, Noonan et al. still recommended the use of the Braden Q scale to assist in the appropriate application of preventive interventions for children at risk of PU.

In another study which examined skin breakdown and redness risk in PICU (Schindler et al., 2007), the Braden Q scale, with a cut-off score of less than 16, did not show any significance. However, this was argued to be a result of nurses' non-adherence to the data collection protocols, and improper documentation of Braden Q risk scores or PU categorisation, particularly during the first days following patients' admission to the PICU.

b) Risk Factors/ Predictors based on Multivariate Analysis

Four major models were established based on the use of binary *LR* analysis. This statistical test facilitates studying the correlation between several predictors (categorical and / or continuous) and one dichotomous outcome. All previously mentioned risk factors based on univariate analyses were entered again into *LR* models. This was important in order to show the most significant predictor of PU development while controlling the effect of the other predictors, something which cannot be done through univariate analysis (Field, 2009).

Significant risk factors based on multivariate analysis are discussed in this section based on the following four *LR* models;

1- Model one: Braden Q Scale sub-items.
2- Model two: Glamorgan Scale sub-items.
3- Model three: General predictors and Braden Q sub-items.

4- Model four: General predictors and Glamorgan sub-items.

i) Model One: Braden Q Scale Sub-Items.

Despite the fact that six out of seven sub-items of the Braden Q scale were highlighted as significant risk factors for PU development based on univariate analyses, none were found to be significant using *LR*. Anthony et al.'s retrospective study (Anthony et al., 2010) reported three sub–items of the Braden Q scale, *mobility, tissue perfusion and oxygenation* – as well as *moisture* - to be significant by *LR*.

ii) Model Two: Glamorgan Scale Sub-Items.

All significant risk factors of the Glamorgan RAS based on the univariate analyses – namely, *mobility, nutrition, equipment pressing on patients' skin* - were entered into *LR* model two. Of these, *mobility* was the only one retained as a significant predictor of PU development among critically ill patients (*OR*= 1.07, 95% *CI* 1.004-1.149, *P*= 0.037). According to this finding, children who had restricted mobility had a 7% higher risk of developing PU than the normally ambulant children, yet this percentage shows almost no difference between ambulant children in regards PU development , since only seven of the total 147 normally ambulant patients developed PU (4.8%) .

Previous studies that have reported the significance of this factor were discussed above in the univariate analyses section. However, none of these used advance statistical tests such as *LR*, except for one retrospective study (Anthony et al., 2010), in which *mobility*, along with another four sub-items, of the Glamorgan scale were revealed by *LR* to be significantly related to PU development.

iii) Model Three: General Predictors/ Risk Factors and the Braden Q Sub-Items.

All significant sub-items of the Braden Q scale (*mobility, activity, sensory perception, friction and shear, moisture,* and *oxygenation and tissue perfusion*), and all general risk factors identified by univariate analyses (*age in days, PEEP level, being on MV, duration on MV≥ 4 days, ICU LOS, GCS score*) were entered into this model.

The model failed to show significant difference between PU, and PU-free patients (χ^2= *17.10, P= 0.105)*. None of these factors were identified to be significant predictors of PU development for this sample.

iv) Model Four: General Predictors/ Risk Factors and the Glamorgan Sub-Items.

All previously identified general risk factors and the significant sub-items of the Glamorgan RAS were entered into this model. Of all of these, *being ventilated for four days or longer* was the only significant predictor of children's risk of developing PUs. Children who had been on MV for four days or longer were at 6 times greater risk than those who stayed ventilated for shorter periods (*OR*= 6.39, 95% *CI* 1.023-39.95, *P*= 0.047). The majority of PU-patients had been ventilated for more than four days (73.7%, n= 14), and spent significantly longer periods on MV than the PU-free patients (Mean± SD= 9.6± 6.1 vs. 5.3± 5.9).

Many studies have supported the findings of the current study (Curley et al., 2003a, Zollo et al., 1996, Yong et al., 2005, Neidig et al., 1989). For example, Neidig et al. (1989) found that the length of time a child spent intubated following open heart surgery was significantly related to the development of occipital PUs. According to this retrospective audit, any child who remained intubated for longer than 7 days would be at higher risk of acquiring PU than those who were extubated earlier (10.1±11.5 vs. 3.4±4.9, P=0.0008).

Curley et al. (2003a) also noticed that children who remained for longer periods on MV were at higher risk of developing category *II and above* PUs, yet this was lower than the risk observed in the current research. According to Curley et al., PU children had 1.06 times the risk of acquiring category *II and above* PUs than the PU-free children, for each 1- day increase on MV (*OR*= 1.06, 95% *CI* 1.03-1.10, *P*<0.001). Another PICU incidence study (Zollo et al., 1996) found that the mean length of duration on MV for paediatrics with impaired skin integrity was higher than that of those with intact skin (Mean± SD= 7.75± 11.01 vs. 3.59± 8.79).

Moreover, in one RCT where *LR* was used (Yong et al., 2005), the duration patients had spent on CPAP ventilation was the only significant predictor of nasal injury development either if using prongs or facial masks on low birth weight neonates (OR= 1.04, P=0.003). These children's risk of developing skin injury based on time spent on MV was still lower than that identified in this research work. However, Yong et al.'s study aimed to measure different types of nasal injury and not specifically PU.

Long periods on MV were thought to be significantly related to PU development, because of their association with patients' immobility and longer periods of ICU LOS. Also, spending longer periods on MV would increase the need for sedation, which might diminish the normal sensory response of patients to pain and pressure for longer periods (Neidig et al., 1989, Curley et al., 2003a, Murdoch, 2002).

From another perspective, longer periods on MV may reflect the acuity of these patients' health conditions who are likely to experience restricted frequency of positioning which, in turn, would increase the friction and shear forces, and then increase the risk of PU development (Neidig et al., 1989).

5.5.3 Predictive Validity of the Applied Paediatric Risk Assessment Scales

5.5.3.1 Glamorgan Risk Scale for Paediatrics

The Glamorgan RAS was able to correctly classify PU-patients and PU-free patients in this study. Based on the ROC, the total score of the Glamorgan RAS showed a significant area under the curve (AUC= 0.79, 95% *CI*, 71-- 87, *P*< 0.001). The current AUC value of the Glamorgan total risk score is lower than has been mentioned previously (Willock et al., 2009, Anthony et al., 2010).

However, the higher AUC value in the two earlier studies might be related to the fact that they depended on the raw data that was used initially to develop the Glamorgan scale. Moreover, the different population of children studied in this thesis (critically ill paediatric patients) might affect the scale's predictive abilities, since it was initially developed to be used in general paediatric wards. Nevertheless, this thesis is not the first

work to report the Glamorgan scale's limited performance in critical care areas (Kottner et al., 2012).

Using a cut-off score of 10, the Glamorgan risk scale demonstrated a perfect sensitivity of 100%, but low specificity of 38%. Whilst the overall Glamorgan total score was the best predictor of PU development, the sub-items *equipment pressing on skin* (AUC 0.71, CI 0.63 – 0.80), and *mobility* (AUC 0.69, CI 0.56 – 0.83) were also effective. However, using a cut-off score of 15 (indicating high risk), the Glamorgan was 100% sensitive, and more specific (43%). Thus, the Glamorgan RAS may be best employed to detect risk among high risk children rather than in low risk settings.

5.5.3.2 The Braden Q Risk Assessment Scale

Using a cut-off score of 16, the Braden Q scale was demonstrated to have a relatively low sensitivity of 47%, and a moderately high specificity of 83% (AUC 0.80, CI 0.72 – 0.89). Whilst the overall Braden Q score was the best predictor of PU development, sub-scores for *activity* (AUC 0.79, CI 0.72 – 0.86), *sensory perception* (AUC 0.78, CI 0.69 – 0.87), and skin *moisture* (AUC 0.77, CI 0.67 – 0.88) were also effective, with almost similar AUC values.

Based on the same cut-off score (16), the Braden Q was shown to have better sensitivity (0.88), but less specificity (58%) in one previous study (Curley et al., 2003b), although it reported almost the same AUC (0.83, CI 0.76- 0.91) as was observed in this thesis. According to Curley et al., only three sub-items of the Braden Q scale were significant, with AUC > 0.7. These were *mobility*, *sensory perception*, and *tissue perfusion and oxygenation*.

The same authors investigated the effect of eliminating non-significant sub-items of the scale on the performance of the total score, under the ROC. The AUC was improved to 84% (CI 0.77-0.91), while sensitivity and specificity were enhanced to 92%, and 59% respectively, where a cut-off score of 7 was used (Curley et al., 2003b).

Comparing the significant Braden Q sub-items in this thesis with those shown in the previous study, all except *nutrition* were also significant. Following the Braden Q total

score, *activity* was the most predictive sub-item in this sample (AUC 0.79, CI 0.72 – 0.86, P < 0.001), whereas *tissue perfusion and oxygenation* was the least predictive of PU risk (AUC 0.66, CI 0.55- 0.75, P =0.02).

One further study which estimated the AUC of the Braden Q risk scores was a retrospective survey which aimed to compare this scale's performance with that of another two scales (Anthony et al., 2010), where, the AUC was noticed to be lower than that described in Curley et al. (2003b) (AUC 0.70).

Nevertheless, as was shown earlier, the Braden Q had a low sensitivity based on the recommended cut-off score of 16 by Noonan et al. (2011). Some authors (Quigley and Curley, 1996, Loman, 2000) have argued that this score would identify only high risk patients, while using a higher cut-off score might help in identifying patients with lower risk of PU. The sensitivity and specificity of the Braden Q scale were considered in this thesis based on a higher cut-off score of 23, which produced values which were more clinically acceptable. The Braden Q scale's performance was improved to 95% sensitive and 66% specific. This score was considered by comparing specificity and sensitivity of the scale total score on different thresholds, where the scale performed the best.

5.5.3.3 Comparing the Predictive Validity of the Glamorgan and Braden Q Risk Assessment Scales

The Braden Q RAS showed a slightly higher AUC than the Glamorgan RAS for this study's particular population (AUC= 0.80 vs. 0.79). However, if overlapping confidence intervals are taken into consideration, this would suggest no significant difference between the two scales.

Nevertheless, the Glamorgan was more sensitive than the Braden Q scale, when the recommended cut-off scores for risk - 16 for Braden Q, and 10 for Glamorgan – were applied (Noonan et al., 2011, Willock et al., 2009). This might be considered a good reason for the Glamorgan scale to be used in paediatrics, since sensitivity is more important than specificity when considering risk measures for any disease or health problem.

Any scale which has the ability to correctly classify children who are at risk, is much more beneficial than one which is able to correctly classify children whose risk scores show they will remain free of ulcers. This is due to the importance of detecting patients at risk, and hence being able to intervene accordingly, over the issue of allocating preventive interventions to those who may not actually be at risk (Ayello and Braden, 2002).

On the other hand, the low specificity of the scale may be seen not as a clue that it has failed to classify patients' level of risk correctly but rather, this value could be affected by the prevention measures and intervention aids provided by nurses (Willock et al., 2008). Since the scale is a measure of the risk of the problem (PU development) occurring, and not a measure of the actual problem's existence (Kottner et al., 2011), any appropriate preventive interventions applied to the children during the study's follow-up period could influence whether the problem actually occurs (Willock et al., 2009, Moore and Cowman, 2008). This does not mean necessarily that these children were not at risk at the beginning, or that the scale failed to estimate their risk according to its scores.

In this thesis, there was no intention to control any preventive interventions applied by nurses to limit PU formation, but this may have been one reason for the low specificity of the Glamorgan scale. Although it was not within the scope of this study to document them, many nursing prevention measures were observed in use within the Jordanian critical paediatric units investigated, especially in the NICU. Examples were frequent positioning and special head and body protective pads, use of which might explain the low frequency of surface-related PU compared with equipment-related ulcers within this unit. However, this phenomenon would require further study before being propagated to neonatal critical units.

For all that it is preferable for clinical use to apply a highly sensitive tool even if having adequate specificity level (Curley et al., 2003b). However, based on using the higher cut-off scores, both the Glamorgan and Braden Q scales have shown improved sensitivity and adequate specificity. With a cut off score of 15, the Glamorgan was found to have perfect 100% sensitivity, and 44% specificity, while using a cut-off score

of 23, of the Braden Q had 95% sensitivity, as well as a considerable specificity value of 66%. These cut-off scores might improve the performance of both scales in the clinical field if such improvements in the sensitivity and specificity values can be backed up by further research among different paediatric populations.

In one study that compared the performance of the Glamorgan, the Braden Q and another paediatric risk assessment scale (Garvin), the authors found that the Glamorgan was superior in terms of predictive validity, although the scales were tested based on the same data set that was used initially to develop the Glamorgan scale (Anthony et al., 2010). In addition, this was a retrospective study, which is not a preferred design for this type of research, because it would not enable the researcher to score different sub-items of the scale more accurately based on direct skin assessment of patients, also, it would be biased by depending on the available documentation by nurses.

One recent study (Long et al., 2011) suggested similarity in both the Glamorgan and the Braden Q RASs, based on the ROC. This study identified both scales as being reasonable classifiers of patients' risk of PU development, though the Glamorgan scale was more sensitive in the studied sample. In the same study, seven out of nine sub-items of the Glamorgan scale, compared with six out of seven Braden Q sub-items, were revealed to be significantly different for PU patients and those who are free of ulcers.

In this thesis, only two sub-items out of nine from the Glamorgan scale were significant based on the ROC in addition to the total risk score, namely *mobility* and *equipment pressing on patient's skin*. Conversely, all except for one 'the *nutrition* sub-item' of the Braden Q scale were assessed as significant.

These findings were much the same when univariate analyses were used to study the correlation between each scale's sub-items and the development of PU in critically ill children, when the *impaired nutrition* sub-item was included as a significant variable of the Glamorgan RAS, in addition to *mobility* and *existence of pressing equipment*. However, *LR* revealed only one Glamorgan sub-item, *mobility*, to be significant while none of the Braden Q sub-items were recognized by *LR* as being significantly related to PU development in this group of children.

The use of both univariate and multivariate analyses in another study (Anthony et al., 2010) revealed that only five sub-items of the Glamorgan scale were significant predictors of PU formation, *mobility, pyrexia, low albumin level, incontinence,* and *existence of equipment pressing on child's skin.* Similarly, only three Braden Q sub-items were noticed to be significant*: mobility, moisture,* and *tissue perfusion.*

A further two values, the positive predictive value (PPV) and the negative predictive value (NPV) were calculated for each scale. According to these values, the Glamorgan scale was correct in classifying 13% of PU-patients of being at risk, while it was 100% correct in classifying not-at-risk patients who really did not develop ulcers later. For the Braden Q scale, it was able to correctly classify 21% of patients at risk of PU, who did develop PUs later, and 94% able to correctly identify patients who were not at risk, and who did not develop PU later on.

Based on these values, the Braden Q scale could be identified as a better classifier of patients at risk of PU. However, sensitivity and specificity measures are considered better indicators of patients' risk than the predictive values, because the latter are affected by the incidence and prevalence rate of all the cases in the sample.

As previously discussed, the performance of the Braden Q among the critically ill population is almost equal to that of the Glamorgan scale, and although the former achieved high specificity with the two cut-off scores tested, the latter was more sensitive. Sensitivity is more important when applying the scale in clinical areas, because of the need to truly detect patients who are at risk, and thus enable nurses to intervene appropriately. This means that the Glamorgan scale could be given preference over the Braden Q scale.

In more detailed inspection of each scale's sub-items, the *mobility* sub-score of the Glamorgan was found to be the most predictive of PU development, either by using the AUC calculations, the univariate or the multivariate analyses. Also, its AUC was almost the same as the AUC for the total risk score of the scale. This raises ideas about the usefulness of using one single sub-item over using the whole scale. Yet, this proposal could not be undertaken without further studies being conducted to support it.

On the other hand, for the Braden Q scale, *activity level* and *sensory perception* were the most predictive sub-scores. However, both failed to show significance in the multivariate analysis. Despite the fact that the *mobility* and *activity* sub–items were tested by both the Glamorgan and Braden Q scales on the same population, only the *mobility* sub-item of the Glamorgan scale was shown to have a significant association with PU development based on *LR*.

This could be explained by the different definition of *mobility* used in each scale. While the Glamorgan scale considers the child's ability to change position, to walk and to move freely as mobility indicators, the Braden Q scale uses the child's ability to change position purposefully as a mobility indicator but ambulation as a physical activity level indicator. Thus, for example, any child who can change position in the bed, but cannot walk out of bed without the help of a nurse, would score normally against the mobility indicators of the Braden Q scale (score 4), yet this child would score 10 for this category in the Glamorgan scale, which would mean that he or she is at some level of risk.

5.6 SUMMARY OF THE CHAPTER

This chapter aimed to highlight the main results of the study without providing excessive detail in regard to numerical findings. It has explained the main findings clearly, in a way which has helped to underline their usefulness or limitations.

Also, this chapter has helped to assess the strengths and weaknesses of the study design and methodological approach. Much strength was added to this study by the fact that a prospective model was used, which is preferable to other study designs. Furthermore, novelty was established because this study was the first to examine PU in children in Jordan and the Arab world.

The findings may help in demonstrating the existence of the problem and its size in paediatrics, when compared with previously published universal data. Also, the characteristics of this particular group of children can be compared with those previously assessed in other countries, such as the USA, the UK, and in Europe. It will provide benchmarking data, which will further the appropriate allocation of health resources, as well as help save time and money.

The distinctive prospective approach in comparing the validity of two major paediatric RASs also contributed to the field of paediatric risk assessment. No previous studies have compared paediatric scales for critically ill patients using this approach. The findings of the risk assessment survey may assist in identifying children, especially in ICUs, as a risk group for PU development as well as adults. In addition, it may highlight the necessity of introducing a specific paediatric RAS in Jordanian hospitals, as well as in other Arabic counties.

Finally, using a more advanced statistical approach to analyse the data can help to identify evidence-based characteristics, and contributing factors which determine children's risk of PU development in this population. The multivariate analysis revealed that the time a ventilated child would spend on MV was significantly related to PU development in children in this study. Many other factors were also significant based on the less restrictive univariate analyses.

On the other hand, this study's generalisability may be affected by its modest sample size, and the population of children included. Recruiting a larger sample size and studying children in other hospital wards, in addition to the ICU, may help in future to improve the reliability of the findings, and their generalisability.

CHAPTER SIX: LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

6.1 A GLANCE AT THE CHAPTER

This chapter introduces the limitations encountered during this research, in both prevalence and incidence studies. Recommendations for clinical, administration and research health care domains are suggested. All identified shortcomings in this research work are summarised, and the addition of this research to the clinical area's existing body of knowledge is discussed. A summary of the concluding observations is drawn based on the research's major findings in its two aforementioned studies.

6.2 RESEARCH LIMITATIONS

Several issues could affect the findings of this research work, as a consequence of using different research designs in both prevalence and incidence studies, despite the fact that maximum efforts were adopted and initiated to minimise such undesired consequences. However, these limitations should be considered when interpreting the findings of the current work, while they could be addressed in future work. These limitations are discussed according to the different research methods used as outlined below.

6.2.1 Prevalence study

Though this prevalence survey is a major contribution to the paediatric PU literature in general, and specifically for Jordan, it has several identified limitations, most notably the small sample, recruited from only one hospital, which might not be representative of the Jordanian population as a whole. This was due to the limited time, money and personnel resources of the research; however, the hospital was chosen carefully, because it is one of the largest university hospitals in all the region and in Jordan, and such university hospitals represent around 10% of the total beds in Jordanian hospitals (MOH, 2011).

Furthermore, regarding sampling design, this was selected by non-probability convenience methods, which might limit the representativeness of the sample of the paediatric population, due to the increased risk of self-selection bias, which is why probability is a more respected approach than non-probability sampling in terms of the confidence that can be placed in the representativeness of the sample (Polit and Beck, 2010).

From another perspective, excluding some paediatric groups from the study sample could interfere with the generalisability of the findings, and under- or over-estimating the actual size of the problem. Excluding burn, isolation, and psychiatric patients was obligatory to the researcher whose priority was to ensure the safety of recruited children and neonates, prevent infection and contamination spread through different surveyed wards, and to reduce unexpected accidents with psychiatric patients. Adults and

outpatients patients were excluded because they were not within the scope of this study. However, excluding some wards/specialities from PU prevalence surveys is not uncommon; this could help in comparing the findings with other studies (McLane et al., 2004, Noonan et al., 2006).

Moreover, the used study design of the prevalence survey itself is not preferred (cross-sectional), because it measures the case of interest (PU existence) at one point of time in one place (Shields and Twycross, 2003). Using cross-sectional design to infer a relationship between two variables (predictor and outcome) is weak (Hoe and Hoare, 2012), so no relationships between variables was sought by this design, whereas cohort study design is preferred; an incidence study was also performed.

This study did not observe the applied preventive interventions for paediatric children, although this was recommended previously (EPUAP and NPUAP, 2009, Willock et al., 2009). Investigating PU prevalence in the presence of applied preventive interventions was argued to help in ascertaining the effect of providing proper preventive methods on the measured size and risk of PU (Willock et al., 2009). However, this study was focused on determining the size of the PU problem among paediatric Jordanian inpatients, to establish an initial perception of the existence and magnitude of this problem in this population. Further work could be done to address the used preventive interventions in this population.

6.2.2 Incidence study

As mentioned in section (2.1), this sample was also recruited from the same university hospital in Jordan, yet the target population was only critically ill children and neonates. Recruiting only this group of children might limit the generalisability of findings to other paediatric groups. Also, the small sample size might affected the power of the findings, regarding the identified significant risk factors of PU occurrence, and the predictive validity of the two utilised risk scales (Braden Q and Glamorgan). However, this sample size was calculated based on using power analysis test to achieve an accepted power of findings (P= 0.80).

Moreover, the used non-probability sampling method might hinder the generalisability of the findings; as mentioned previously, probability sampling is preferred over non-probability methods, since the former usually lacks representativeness of the target population (Polit and Beck, 2010). However, the used consecutive sampling technique has been found to be better than the usually used convenience sampling, especially if subjects were recruited over a long period of time, because all target subjects who meet the inclusion criteria are recruited in the sample (Polit and Beck, 2010).

Excluding some patients from the sample would reduce the generalisability of findings to these patients, or potentially cause under- or over-reporting the PU incidence rate, such as those in isolation or those who did not give consents. Also, some research procedures, like including only children and neonates who achieved at least two consecutive assessments, might cause the exclusion of further patients, who might have different features that could affect the findings of the study.

From another perspective, the used research design had its limitations. Using observational cohort design limits the ability to infer causal relationships between identified risk actors and PU formation; only experimental design can do so (Polit and Beck, 2010). However, the used prospective cohort study is more preferred than using cross-sectional or case-study research designs (Hoe and Hoare, 2012). On the other hand, non-experimental design could not control the effect of extraneous variables while studying the problem of interest (Polit and Beck, 2010); in this study, the researcher was unable to control the effect of applied preventive interventions on the observed outcome (PU formation). The effect of proper prevention protocols reduces PU incidence rate, as well as limiting the measured specificity of the risk assessment scales (Willock et al., 2009, Moore and Cowman, 2008).

Additionally, as in the previous section, no data was gathered about the applied interventions and prevention methods in these wards, which might limit the ability to infer any possible relation between using these methods and the actual size of the problem. Further future work is needed to investigate these in paediatric PU inpatients in Jordan.

Finally, the used risk assessment scales (Braden Q and Glamorgan) were not formerly tested for the Jordanian paediatric population, but some studies that show them to be promising tools over other identified paediatric RASs; the validity and reliability of these two scales was reported in previous studies (Quigley and Curley, 1996, Curley et al., 2003b, Willock et al., 2008, Willock et al., 2009, Anthony et al., 2010), yet no evidence was achieved to conclude the best scale to measure paediatric PU risk until the moment.

6.3 RESEARCH RECOMMENDATIONS

Despite the study limitations given in the preceding section, the study is still deemed important for paediatric nurses, establishing a better understanding of PU size, its contributing factors and the predictive validity of the most commonly used paediatric RASs. However, as it is a new subject being explored, suggestions for numerous recommendations at the clinical, administrative and research domains are presented below.

6.3.1 Clinical domain

Periodically conducting prevalence and incidence studies would increase nurses' attention on the PU problem in paediatric care. It is not unusual for nurses to report PU as an adult problem, yet on-going research proved that PU occurs in children and more commonly in neonates and young age patients, as well as among children residing in paediatric critical care units.

Using RASs specifically designed for paediatrics is recommended, since these tools prove validity and reliability, and because they would be able to classify children into risk groups with respect to their variant developmental levels, and the unique characteristics of each age group.

Also, as noticed from the findings of this research, PU usually occurs at the early days of admission, so encouraging the use of the risk scales as early as possible, definitely within 24 hours of admission, and hence intervening sensibly based on the patients'

risk, through providing the most appropriate and accessible prevention aids and surfaces available.

In Jordan in general, and specifically in the study setting, the adult Braden is the used scale to assess risk in children. However, although not documented in this research, filling the scale in was not undertaken by hospital' nurses most of the time, which could be related to the ICU nurses' perception that skin assessment is not a priority for children in critical conditions. Using this scale was reported before as not being suitable for paediatric populations (Kohr and Curley, 2009); this might increase the risk that such children be misclassified, resulting in inadequate application of preventive interventions.

So this study could encourage Jordanian hospitals to adopt a credible PU classification system such as that of the EPUAP, as well as adopting one predictive tool specifically designed for paediatrics. The Jordanian nurses' practice might improve by identifying true risk factors of PU, and an evidence based preventive measures.

6.3.2 Administration domain

First, the findings of this research recommended that health organisations' administrators and managers adopt a yearly survey of PU among paediatrics. This should also be supported by on-going education and training sessions for nurses on the method of assessing and documenting PU. These sessions would enhance nurses' awareness of the existing problem, increase their abilities on using qualified risk scales, classifying PU categories' appropriately, and most importantly how to intervene correctly and promptly.

Next, nurses' documentations habitually show no appropriate categorisation of existing PU, and often there is no documentation of identified PUs at all in patients' records, leading to the recommendation that internationally accepted classification systems of PU is adopted, such as the EPUAP and the NPUAP classifications, as there is no national classification system of PU used in Jordanian hospitals. It is also recommended

that a paediatric specified RAS usage, such as the Braden Q or the Glamorgan scales, is applied in paediatric wards, rather than using adult scales, since it is more credited and suitable for children's unique developmental characteristics.

Finally, on-going support for nurses who report and intervene properly and swiftly to PU cases should be granted. Furthermore, the proper intervention and prevention aids and surfaces should be available and accessible for any child who appears to be at risk of PU development, based on nurses' judgment and RAS' use. Identifying children who are at risk of PU but withholding any prevention reasonably would have negative consequences on both the patient health and wellbeing and on the health organization's material and financial resources.

6.3.3 Research domain

As addressed before, further research work is recommended regarding the incidence and prevalence of PU in paediatric population, since little work has been done in this area worldwide, particularly in Jordan and the Arab world in general, especially in performing a prospective incidence study with adequate statistical inferences. The findings of this work could be enhanced by use of a larger sample size, including general paediatric patients' cases, as well as a more credible research design, such as experimental design.

Furthermore, as this work was an initial step toward investigating the PU practice of Jordanian paediatric nurses, to shed light on its existence, magnitude, and how to identify risk, further future work is recommended on the same population to investigate the existing prevention and intervention protocols adopted by paediatric units, to assess their types, availability, and their usefulness as well as applicability for this particular population, since proper assessment is the first step in good prevention.

The effect of the existing prevention aids could be described in terms of children's actual development of PUs, specifically on those who were classified initially as being at risk of PU occurrence, but did not develop a PU. The effect of such proper

intervention on the measured specificity of the RAS used should also be researched further.

As observed in this study, there is another type of skin damage that was very prevalent in paediatric patients, precisely in neonates: adhesive injuries. Such injuries had a considerably high incidence in the studied NICU population for this research work, which could result from tapes and other adhesive products used to secure nasal CPAP, NG tubes, endotracheal tubes or IV cannulas. The identification of this prevalent problem warrants the use of further precautions by nurses caring for neonates, and further attention from researchers.

Finally, as PU is regarded as an adult-only problem in Jordanian hospitals, further work should be commenced to explore the paediatric nurses' knowledge and attitudes toward PU assessment and prevention; any actual lack of knowledge identified in these nurses should be amended, attitudes should be improved, and prompt clarification of the problem should be issued.

6.4 CONTRIBUTION TO KNOWLEDGE

This research is the first of its kind in Jordan and the broader Arab world. Only two studies about PU have been conducted in other Arab countries previously (Abou El Enein and Zaghloul, 2011, Saleh et al., 2009), and only one in Jordan (Tubaishat et al., 2011), yet all these were related to the adult population.

Moreover, this is the third of another two prospective incidence studies of PU in critically ill paediatrics (Curley et al., 2003a, McCord et al., 2004), and another two specifically for NICU patients (Fujii et al., 2011, Huffines and Logsdon, 1997), although it has a different non-experimental observational cohort design than the case control study of McCord et al. (2004), which also did not measure the incidence rate of PU in this population, and had more variable sample age groups compared with Curley et al.'s (2003a) sample, which consisted of children aged from 21 days up to 8 years only.

On the other hand, the latter two studies had smaller sample sizes, and were only designed to measure PU in neonates, while Huffines and Logsdon' research (1997) was only a pilot study to assess the reliability and predictive validity of their newly developed NSRAS.

From another perspective, this is the first study to use prospective design to compare two paediatric RASs predictive validity in critically ill paediatrics, except for one study which compared the performance of the utilised two scales in general wards (Long et al., 2011), but this was an abstract paper. Another retrospective study (Anthony et al., 2010) compared these two scales with another scale (Garvin), yet, its findings could be limited by the nature of the used research design, and by the use of the raw data initially utilised to develop one of the tested scales (the Glamorgan).

Because of the paucity of paediatric PU studies in general, and in Jordan specifically, this study could be the groundwork for other researches in relation to this area, and a foundation for Jordanian and Arabic paediatric nursing studies on PU.

Moreover, this study confirms the PU occurrence in paediatric population which might improve the current practice regarding PU prevention policies in Jordanian hospitals. By comparing the practice in Jordan with other worldwide practice measures regarding PU care and prevention, an evidence based methods can be adopted, while outdated prevention methods can be stopped or reduced; such as massage of PU area. Also, repeating yearly prevalence audits would increase the awareness of Jordanian nurses on the PU problem, while at the same time would help in assessing the effectiveness of the used preventive measures when comparing different prevalence rates in one setting over several years.

6.5 **RESEARCH CONCLUSION**

The prevalence rate of PU in this paediatric population was found to be higher than in most previous research, which could be a result of including device-related ulcers in calculating the PU prevalence rate. Prevalence studies which included this type of ulcers

showed even greater prevalence (Schluer et al., 2009) than this research. Higher prevalence rate in other studies was attributed to including other types of skin breakdown in calculating PU prevalence rate (Suddaby et al., 2005). Moreover, the fairly high prevalence rate in this research could be attributed to the larger number of children who are younger than one year old, who represented more than half of the prevalence sample, since these children were advised previously as being at higher risk of PU formation than other children groups.

In the incidence study, the incidence rate in the critically ill children and neonates was lower than previously reported, which could be related in some way to the variation between this study and previous studies in the number of raters, acuity of children cases in these units, proper prevention programs applied specifically in NICU, which resembled the largest portion of the sample, as well as using different terms and meanings of PU and skin breakdown. Furthermore, Hawthorn effect might reduce the actual size of the problem, since nurses would pay more attention to PU assessment and prevention during the study period conduction, which could lower that actual incidence rate.

However, regarding the pointed intervention and prevention protocols, its appropriateness and effect on PU incidence rate reduction cannot be guaranteed, since this type of data was not collected or analysed for this research work, and this was only based on the researcher's own observation.

Based on the discussed findings in previous chapters, there was no significant difference between the Glamorgan and the Braden Q risk scales regarding their predictive abilities of PU occurrence in critically ill children and neonates. Though the Braden Q had shown a little greater AUC of the ROC than did the Glamorgan, taking the overlapping confidence intervals of these two scales had suggest no significant difference in their performance.

Moreover, though the Glamorgan scale, based on the suggested cut-off score of risk by authors, showed higher sensitivity than did the Braden Q, it had a lower specificity. However, sensitivity was argued by previous research to be with higher value for the

clinical use than the specificity value, since prioritising child health risk of PU occurrence, hence preventive interventions application is more crucial than proper allocation of efforts and health resources.

On the other hand, considering higher cut-off scores of the two scales (23 for the Braden Q and 15 for the Glamorgan) significantly improved the sensitivity of the former scale, while the 100% sensitivity of the latter remained the same. Adequate specificity was revealed by both scales. These cut-off scores was suggested based on comparing the different sensitivities and specificities thresholds' of each scale based on the ROC.

Furthermore, considering logistic regression models; the Glamorgan sub-score of 'mobility' was manifested as the only significant predictor of PU in this group of children, while none of the Braden Q sub- scores was significant. This could raise the question of the benefits of using one issued significant predictor rather than using the whole scale in predicting paediatrics risk of PU, especially as this sub-score' AUC was almost the same as that of the total risk score; however, this needs further research.

In addition, a newly allocated risk factor of PU development in this research work was suggested as a possible further enhancement in the two used scales' sub-items predictive abilities: the duration the child spends on MV, particularly in this population of critically ill children. Although such a predictor could improve the scale ability to assess children's risk, the risk factor would not be appropriate as a sub-item in any scale designed to measure PU risk in a general paediatric population, since MV is a feature applied only to those who cared for in special care units.

Considering longer periods of time on MV (longer than four days/96 hours) was suggested previously in paediatrics literature, though applying this to all paediatrics would need further work with a larger sample size, and on diverse children and neonatal specialities, including general hospital wards.

6.6 **SUMMARY**

This chapter emphasizes the main limitations regarding the incidence and prevalence studies, the recommended implications for different health care domains, and the unique addition of this work to the paediatrics PU body of knowledge, specifically in the risk assessment field. Furthermore, the main conclusions related to the thesis major themes were summarised; the identified size of PU problem in this population was highlighted in terms of previous related literature; and the significant contributing factors of PU formation in critically ill patients were clarified, and the predictive validity of both utilised RASs were stated for this population.

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Appendix 1.1: Table of databases searched, keywords, and number of hits.

Keywords	Medline	CINAHL	BNI	ASSIA	WOK	ASP	COCHRANE
Pressure ulcer prevalence data							
Pressure ulcer	9618	8880	1099	1558	2169	2109	1141
Pressure ulcer+ prevalence	739	723	85	127	340	197	27
Pressure ulcer+ prevalence+ paediatric	6	4	4	7	7	7	2
Pressure ulcer+ prevalence+ child	39	48	3	2	6	4	2
Pressure ulcer incidence data							
Pressure ulcer	9618	8880	1099	1558	2169	2109	1141
Pressure ulcer+ incidence	913	833	116		255	243	146
Pressure ulcer+ incidence + paediatric	6	4	5	3	5	5	3
Pressure ulcer+ incidence + child	50	40	6	7	6	2	5
Pressure ulcer risk data							
Pressure ulcer	9618	8880	1099	1558	2169	2109	1141
Pressure ulcer+ risk	2661	2974	298	432	742	693	226
Pressure ulcer+ risk + peadiatric	19	20	10	9	13	17	4
Pressure ulcer+ risk + child	114	131	16	21	12	24	8
Pressure ulcer + risk factors	80	70	95	118	353	259	103
Pressure ulcer + risk factors+ paediatric	1	2	2	1	5	8	2
Pressure ulcer + risk factors+ child	3	3	5	5	5	11	3

Pressure ulcer+ risk scale	203	711	80	105	270	88	36
Pressure ulcer+ risk scale+ paediatric	4	6	7	5	6	2	1
Pressure ulcer+ risk scale+ child	10	41	7	9	5	5	3
Pressure ulcer+ Braden Q	11	14	3	4	5	2	2
Pressure ulcer+ Glamorgan	26	5	5	10	2	6	2

*** WOK:** The Web of Knowledge, **ASP**: The Academic Search Premier (EBSCO), **ASSIA**: Applied Social Sciences Index and Abstracts, **BNI**: British Nursing Index, **CINAHL**: the Cumulative Index to Nursing and Allied Health Literature.

Appendix 1.2: Quality scale used to critique the included articles in the literature reviews.

Author and title: _____
Date: _____

	Good	Fair	Poor	Very Poor	Comment
1. Abstract and title					
2. Introduction and aims					
3. Method and data					
4. Sampling					
5. Data analysis					
6. Ethics and bias					
7. Findings/results					
8. Transferability/generalisability					
9. Implications and usefulness					

1. Abstract and title: Did they provide a clear description of the study? **Good**: Structured abstract with full information and clear title. **Fair** :Abstract with most of the information. **Poor** :Inadequate abstract. **Very Poor** No abstract.
2. Introduction and aims: Was there a good background and clear statement of the aims of the research? **Good** Full but concise background to discussion/study containing up-to date literature review and highlighting gaps in knowledge. Clear statement of aim AND objectives including research questions. **Fair** Some background and literature review. Research questions outlined. **Poor** Some background but no aim/objectives/questions, OR Aims/objectives but inadequate background. **Very Poor** No mention of aims/objectives. No background or literature review.
3. Method and data: Is the method appropriate and clearly explained? **Good** Method is appropriate and described clearly (e.g., questionnaires included). Clear details of the data collection and recording. **Fair** Method appropriate, description could be better. Data described. **Poor** Questionable whether method is appropriate. Method described inadequately. Little description of data. **Very Poor** No mention of method, AND/OR Method inappropriate, AND/OR No details of data.
4. Sampling: Was the sampling strategy appropriate to address the aims? **Good** Details (age/gender/race/context) of who was studied and how they were recruited. Why this group was targeted. The sample size was justified for the study. Response rates shown and explained. **Fair** Sample size justified. Most information given, but some missing. **Poor** Sampling mentioned but few descriptive details. **Very Poor** No details of sample.
5. Data analysis: Was the description of the data analysis sufficiently rigorous?

Good Clear description of how analysis was done. Qualitative studies: Description of how themes derived/ respondent validation or triangulation. Quantitative studies: Reasons for tests selected hypothesis driven/ numbers add up/statistical significance discussed. **Fair** Qualitative: Descriptive discussion of analysis. Quantitative. **Poor** Minimal details about analysis. **Very Poor** No discussion of analysis.
6. Ethics and bias: Have ethical issues been addressed, and what has necessary ethical approval gained? Has the relationship between researchers and participants been adequately considered? **Good** Ethics: Where necessary issues of confidentiality, sensitivity, and consent were addressed. Bias: Researcher was reflexive and/or aware of own bias. **Fair** Lip service was paid to above (i.e., these issues were acknowledged). **Poor** Brief mention of issues. **Very Poor** No mention of issues.
7. Results: Is there a clear statement of the findings? **Good** Findings explicit, easy to understand, and in logical progression. Tables, if present, are explained in text. Results relate directly to aims. Sufficient data are presented to support findings. **Fair** Findings mentioned but more explanation could be given. Data presented relate directly to results. **Poor** Findings presented haphazardly, not explained, and do not progress logically from results. **Very Poor** Findings not mentioned or do not relate to aims.
8. Transferability or generalizability: Are the findings of this study transferable (generalizable) to a wider population? **Good** Context and setting of the study is described sufficiently to allow comparison with other contexts and settings, plus high score in Question 4 (sampling). **Fair** Some context and setting described, but more needed to replicate or compare the study with others, PLUS fair score or higher in Question 4. **Poor** Minimal description of context/setting. **Very Poor** No description of context/setting.
9. Implications and usefulness: How important are these findings to policy and practice? **Good** Contributes something new and/or different in terms of understanding/insight or perspective. Suggests ideas for further research. Suggests implications for policy and/or practice. **Fair** Two of the above (state what is missing in comments). **Poor** Only one of the above. **Very Poor** None of the above.

Authors	purposes	Sample	Study design	Inclusion criteria	Exclusion criteria	Data collection tools	Prevalence rate	Most affected sites	Remarks
1) McLane et al. (2004) **USA**	- To document the prevalence of PU & other skin breakdown in paediatric inpatients.	1064 child from 9 children hospitals	Descriptive, One day prevalence study.	To tolerate skin assessment in supine & prone positions. - be inpatient. - Age from birth up to 17 yrs old.	- Bum and psychiatric units. Age 18 years & older. Out-patients. No signed consent. Being too unstable.	- The Braden Q Scale. The neonatal/ infant Braden Q scale was developed for this study. Data collection form. Interr-ater reliability quiz. - Using NPUAP for PU staging. - Data collection included skin assessment for each subject, and a chart review. When PU exists, data about category, location, and treatment were documented.	Prevalence rate of PU was 4% (n= 43), 92% of them were partial thickness, and 66% were facility associated. -the children ICUs PU prevalence was 8.7%. - Other SB prevalence was 14.8% (n= 158).	- Head (31%, n= 13), seat (20%, n= 9), and feet (19%, n= 8). - Most affected sites with SB were: seat (35%), foot (20%), and upper extremities (18%).	Other SB included; diaper dermatitis, skin tears, and IV extravasations.
2) Dixon & Ratliff (2005) **USA**	- To identify prevalence rate in one hospital.	From five paediatric inpatients units (PICU, NICU, rehabilitatio n, and two acute care units).	Two prevalence studies with one year separation in 2003/2004, in one 95 paediatrics' beds in one larger referral hospital.			- Two WOC nurses had completed skin assessment for each child in each unit. - The NPUAP staging system was used.	- In 2003, the prevalence rate was 3% (2 patients developed ulcers out of 77). In 2004, the prevalence was 4%, (3 patients developed ulcers out of 79. - For the 2 years, 3 PUs were stage I, and 3 were un-stageable.	Heel was the most prevalent site for PU (n= 3), then sacrum, nares, and ankles (n=1 for each). - All PUs were identified in PICU, NICU, and rehabilitation unit.	This article has recommended the usage of paediatrics RAS, and the nurses teaching regarding PU assessment and prevention.

3) Suddaby et al. (2005)	To establish simple paediatric SB risk assessment tool that can be applied in acute units.	347 paediatric patients from PICU, medical-surgical, oncology and adolescent units. .	Five quarterly point prevalence surveys in one single hospital over 15-months period.			- The Starkid Skin Scale was used which is adopted and revised from the Braden Q scale by Two CNS. - All patients were physically assessed for SB, If breakdown was identified; it was scored using the AHCPR classification system. The number and location were also recorded, as well as, any implemented intervention.	- 80 patients had 100 sites of breakdown (23%). - The majority (77.5%, n= 62) was described as category I, the Prevalence of SB in PICU is 42%, (n= 21).	Most common areas were buttocks (25%, n= 25), perineum (19%, n=19), & occiput (8%, n= 8).	- Higher prevalence in PICU than was founded by previous studies, as a result of considering medical devices as significant risk factor for SB. also, considering diaper dermatitis as category I SB.
4) Noonan et al. (2006)	To describe the range of alterations in skin integrity and skin care of hospitalized infants and children	Total surveyed patients were 252.	One day skin prevalence audit in 2005, data were collected on all 15 inpatient units in a university-children's hospital.	All listed inpatients at the day of the audit were included.	Patients over 18 years of age on day of admission, Patients who were dying, and Patients in psychiatric unit.	- Audit tool developed by the authors, and include 12 elements: the use of pulse oximeter, peripheral IV catheters, nasally inserted tubes, and/or any other invasive tubes, Incontinence, tracheostomy, ostomies, incisions/wounds, epidermal stripping, skin abrasions, pressure ulcers, and any other alterations in skin integrity. - Pressure ulcers staged according to NPUAP. PU risk according to Braden Q scale, with Cut- off score as 16.	- six percent (n=14) of patients had a Braden Q score ≤ 16. - Four patients with PU were identified, resulting in a 1.6% prevalence rate. - Total prevalence= 6.7%, n= 17, (PU+ device –related ulcers).	- One patient had a Stage II PU over the knuckles on both hands, and one patient had a Stage II pressure ulcer on right heel. - Two infants had occipital ulcers: one was Stage I, and the other had PU could not be staged because it was covered with eschar.	- Extra 10 patients were found to have device related ulcers from O2 probe (9%) and additional 3 patients had ulcers from other medical devices. 20 patients had tape stripping and further 20 had abrasions. - Adding skin injuries to PU and device –related ulcers would resulted in 12.3% prevalence (n=31).

5) Nie (2008)	To establish a prevalence rate in one tertiary paediatric medical centre.	266 assessed inpatient children	One day prevalence survey in one hospital in 2007.	Patients admitted to ICU, and medical-surgical units.	None	- Identified ulcers were documented for category, location	- Twenty two children had had PUs, prevalence rate= 10.7%.19 patients had facility acquired ulcers, with 9.2% prevalence rate.	Not mentioned.	- A plan for another prevalence survey is intended to measure the outcome of introducing preventive interventions in 4 high risk units, 2 ICUs, one MV unit, and one rehabilitation unit.
6) Schluer et al. (2009)	- To identify the PU prevalence in paediatrics' settings. - To highlight the risk population, and the predisposing factors for PU development.	A convenience sample of 155 inpatients, 27% of them (n= 41) were neonates.	A multicentre, descriptive point prevalence study was conducted in four paediatric hospitals on 2006.	- should be inpatient at least for one day before the survey. - Age from birth- 17 years old.		- The instrument of Bours et al. (1999) was used Which include: - Characteristics of institution, the ward/ team, and patients (Demographical and clinical). -Risk according to Braden. - Severity based on EPUAP. - Document the preventive interventions that were already in place.	- According to the tool used, 100 children had found at risk for PUs (64.5%). - Prevalence rate was 27.7% (n= 43). - Prevalence rate of Grade + II and PUs was 4.5%. - 35% of all children in risk group did developed PUs (n=35), and 8 more children from the non-risk group did developed PUs.	- Nearly half of the pressure ulcers were located in an anatomic area which cannot be precisely specified (n = 25, 43%) then heels and ankles, ears.	The limitations of the study were: the Small sample size, heterogeneity of wards involved (51 from medical unit (33%), 33 surgical (21%), 30 in rehabilitation (19%), As well as, the absence of reliable and valid RAS.

* AHCPR: Agency for Health Care Policy and Research, WOC nurse: wound and Ostomy care nurse, SB: skin breakdown.

Appendix 1.3: Summary of the Paediatrics' Prevalence Studies

Authors	purposes	Sample	Study design	Inclusion criteria	Exclusion criteria	Data collection tools	Incidence rate	Most affected sites	Remarks
1) Neidig et al. (1989)	- Identify RF of occipital PU in paediatrics following open heart surgery. - Design nursing interventions to relief shearing and pressure from the occiput/ scalp.	- 59 infants and children who survived open heart surgery.	Retrospective chart audit.	All children and infants who survived open heart surgery in the period June 1984- June 85.	No patients were excluded	- PU' development was assessed by admission assessment forms, OR assessment, entire PICU stay, and the first 24 hr post op. In general paediatric Unit. - Lesions classified by the California Decubitus Ulcer Classification.	- Incidence rate was 16.9% (6 infants & 4 children). - All PUs was partial thickness.	All PUs were occipital. One heel ulcer was developed in one child.	- After implementing the designed prevention protocol (head positioning Q 2 hrs, applying synthetic sheep skin), the incidence of PU had decreased to 4.8% (one child of 21 patients within 6 months period).
2) Zollo et al. (1996)	- To describe the incidence and severity of SB in PICU population. - To identify risk factors associated with SB in this population.	Data were collected on 271 of 357 consecutive admissions during an 18 weeks period.	A prospective matched case control study On 14 bed' PICU over 18 week's period.	Each child admitted to the PICU during the study period was eligible to inclusion.	None mentioned	- Daily assessment of skin: any changes in integrity, condition, location and severity. - Categorisation based on NPUAP, catgeroy 0 (no SB) and 1 (blanchable erythema) were added to allow investigators to identify control subjects and cases in which the erythema is temporary. - Each child with SB (category 1 or greater) was matched for date of admission with a control child (category 0).	- Altered skin integrity occurred 116 times in 71 patients (incidence rate: 26%). - Twenty cases (7%) of all subjects had developed SB stage 3 or greater.	- Altered skin integrity was mostly in nose (28.4%) followed by buttocks (13.97%) then occiput (12.07%). - The least affected area was heel (3.45%).	- the frequency of observed skin alterations was affected by: - Nurses awareness that their behaviours were observed. - Lack f follow-up after PICU discharge. - Black children might be underestimated in recording stage 1 and 2 ulcers, so, white race could be a fake risk factor
3) Huffines & Logsdon. (1997).	To test the reliability and predictive validity of the NSRAS (Neonatal Skin Risk	Convenient sample of 32 neonates in a neonatal intensive care unit (NICU)	A descriptive pilot study: data collection over 3 month's period.	Participants are eligible for the study if they didn't have any existing SB or lacerations on their skin.	Neonates were excluded if they had any genetic dermatological conditions.	- One author (Huffines) and the primary care nurse for a neonate rated each neonate separately by using NSRAS. - Each neonate's skin was assessed after 24 hrs of	Six (19%) of the 32 neonates developed SB during observation period.	Not mentioned	Development of the scale based on the Adult Braden Scale.

	Assessment Scale) which developed by the authors.					delivery, daily for 7days, and weekly for 2 months or until discharge or the development of SB. - Tow instruments used: the demographical data sheet and the NSRAS.			
4) Waterlow (1997)	To investigate if PU is a problem in paediatric, and the possibility of designing RAS for children based on Waterlow cards.	Around 302 paediatric patients aged from neonates up to 16 years old.	Multisite prospective incidence study.		Day cases patients.	- Assessment form was developed based on the Waterlow cards and modified to fit paediatrics. - Teaching program was applied to involved nurses in the survey. - Assessment done on admission and repeated every two days until discharge.Demographical data was gathered on admission. - No scoring system was used initially, yet, a risk score was applied to each assessment sheet after the child discharged.	Seventeen babies and children developed 33 ulcers (5.6%).	Heel (n= 5), followed by leg, elbows, buttocks, and ankle concurrently (n= 4).	The used scale based on Waterlow adult cards.
5) Willock et al. (2000) UK	To identify the prevalence and incidence of PU in paediatrics.	Sample for incidence study were 82 patients (PICU, neurosurgical & orthopaedic). In prevalence: a 183 patients (from all wards in the hospital).	Incidence part: a prospective cohort study over one month. - Prevalence: one day point prevalence conducted by two nurses two months later.			- Data collection tool was established Based on adult literature; it consist of 26 items in the form of 'tick a box' questionnaire. - Slightly modified version of Torrance (1983) classifying scale was used. The tool was piloted on 10 children, slight modifications were done.	- Incidence rate→7.2% (n= 6).all except for one from PICU. The Prevalence→ 6.5% (n=12). Over Third of them were from PICU. - In the incidence; 3 patients (3.6%)	The most frequent sites of Pressure injury were the occipital area, heal and ears. 3 of 4 children with occipital PU were under 1 year of age.	- Small sample size for both incidence and prevalence. - Reliability between examiners in the prevalence part was established.

							and 4 (2.1%) in the prevalence had sustained SB (category≥2)		
6) Baldwin (2002)	To determine the incidence & prevalence of PU in children.	- 224 Questionnaires sent, 55 questionnaires returned, 40 used for incidence, and 51 for prevalence.	Mail national survey of 234 members of four paediatrics specific health care databases in USA.	Not mentioned	Not mentioned	Questionnaires were sent asking for the following information: - No. of current inpatients paediatrics (1998). - Annual paediatrics admission. - No. of children admitted with PU, or who developed PU during their admission. - Demographical data.	- Of 4429 inpatients, 21 had PUs. The prevalence rate= 0.47%. - Of 115, 870 inpatients, 337 patients were documented had developed PUs, incidence rate= 0.29%.	- Sacrum/ Coccyx were the most frequent site, then heels. - Of the above the waist ulcer, occipital ulcers had accounted for 65%.	- This study had low response rate (25%). - Children were found to have the same mechanism of PU formation in adult and same risk areas.
7) Murdoch (2002) Northern Ireland	- To test the efficiency of introducing a new prevention tool, the cut-foam mattresses on grade 3 and 4 PU development in one PICU.	-Retrospective part: the sample was 750 PICU's admissions (may1997-99). - A prospective: sample was 790 PICU's admissions (may 1999-2001).	Case study, followed by retrospective incidence study and a prospective audit.	Only children who referred to the TVN with grade 3 or worse (4 or Eschar).	Excluding PUs with grade less than 3.	- Nursing and medical notes used for the retrospective audit. - Grading based on the CREST* Wound Management group 1998. - An intervention done by introducing cut-foam mattress. - A prospective study conducted from 1999-2001.	- Of the 750 PICU's admissions (retro), 7 patients were referred to TVN. The two year Incidence was 0.93%. - Of the 790 PICU' admissions (pro.), only 2 children have reported to had PU grade ≥ 3, giving a two yearly incidence of 0.25%.	- The ulcers were in a variety of areas including: occipital, sacral and heels.	Limitations: - exclusion of grade I & II of PUs. - considering grade I as blanching erythema.

8) Samaniego et al. (2003)	To evaluate the existing pressure ulcer/wound program used in one hospital wound clinic	69 patients age from birth -19 years visited the clinic, 50 of them had PU	Retrospective exploratory study, over 1 year period (all medical records of patients who had been seen in the hospitals wound clinic in 1999).	Sample divided into 2 groups: acute wounds, and pressure ulcer. PU only reviewed.		- Variables were taken from medical records. - Documentation of PU taken from nursing wound assessment/ staging documentation form and the photography form, Include: stage, cause, assistive device and location. - Retrospective Braden score were calculated finally. - Staging was based on Wound Ostomy Continence Nurse society (WOCN) and NPUAP. - Braden scores associative factors were extrapolated from the wound documentation.	Incidence rate was 14.6%.	- The Most affected areas were in lower extremities, feet, sacrum, and iliac crest. - Most PU were home acquired; only 4 were hospital acquired.	- Small sample size. - Retrospective study based on recorded data.
9) Curley et al. (2003) USA	- To describe the incidence, locations and RF of PU development in the PICU patients. .	Convenience sample of consecutive 322 PICU patients obtained from three PICUs (from September 1998- July 2000).	A multisite prospective cohort study on 3 PICUS.	- All included PICUs patients should be in bed rest for at least 24 hrs. - For the equal distribution of patient's ages in the 3 sites, MAX no. of patients is 30 on each age group: Infants (21 days to 12 months).Toddler (12 to 36 months). Preschool (3 to 5 years). Young	- Patients admitted to PICU with pre-existing PUs. - Intra-cardiac shunting and/ or unrepaired CHD patients.	- Five data collection tool used: The Braden Q Scale, PRISM III score, The PCPC: to check cognitive ability, The POPC: to check overall physical morbidity, and The Skin Assessment Tool: to record the absence or presence of PU on bony prominence sites. NPUAP used., and Only category II+ PUs were included. - Two nurses blinded to others' scores and assessments, had assessed each patient, 3 times /	- A 27% (n= 86) incidence of PUs in a paediatric acutely ill patient group was founded. - Grade II/ III PU occurred in 60 patients (19%). - An additional 27 device-related ulcers have been reported.	- Of the 60 stage II/ III PUs, 19 (32%) involved the patient's head. - category III PUs had involved the patient's occiput, ear, chest and/ or coccyx.	Limitation may include: - Increase nurses attention and preventive measures for PUs. - These results not applicable on children with cardiac shunts or unrepaired congenital heart diseases.

				school (5 to 8 years). The data collection process had ranged from 11 to 17 months in each site.		week in first 2weeks, then once weekly until discharge. Initial assessment done within few hours of enrolment.			
10) Schindler et al. (2007)	- determine the incidence of SB. - Compare PU' patients & PU free patients' characteristics. - Measure sensitivity & specificity of Braden Q Scale.	401 distinct ICU stays for 373 patients	- Prospective cohort study conducted in PICU at one children hospital. - Follow up period of 15 weeks for every patient who remained in the PICU.	All patients admitted to PICU from April 15 - July 15, 2005.	No patients were excluded	- Daily Braden Q Score, and documentation of SB (type & description), filled in once at admission, then every 24hrs throughout the PICU stay. Demographics. and the PRISM II scores.	- SB occurred in 34 of these stays (8.5%), redness in 25 (6.2%), and SB and redness together in 13 stays (3.2%). - Overall incidence was 18%.	None mentioned	This study Was unable to evaluate sensitivity & specificity because of insufficient data.
11) Fujii et al. (2011) Japan	- To identify the incidence of PU development in neonates admitted to NICU. - To clarify the RF of PU development for this population.	81 neonates had met the inclusion criteria, of 211 patients admitted to the NICUs.	A multisite prospective cohort study of 7 NICUs, from January to November 2006.	All infants admitted to the NICU, and cared for in incubators, and did not have SB when recruited for the study.	Infants in open cot, or had SB, and unsuitable infants according to the nurse' ad physician' opinions.	- Skin examination was done daily by nurses. - If PU developed, the location and stage were recorded. used NPUAP. - Demographical data and RFs were collected from observation and patients records by a researcher, three times/ week. - Apgar score, Braden Q score, and Dubowitz neonatal maturation assessment score were calculated.	- Incidence rate = 16% (n= 13). - P <0.05. - 14 ulcers occurred in 13 patients during 11 months study period.	- Most common location was the nose (50%, n= 7), followed by foot (14.2%, n= 2).	- Hawthorne effects may be lowered the incidence rate of the study, because of the nurses awareness of the researcher who directly assessed the subjects' skin. - Small sample size.

***** CREST: Clinical Resource Efficiency Support Team wound management group 1998, CHD: Congenital Heart Diseases, PRISM score: Paediatric Risk of Mortality Score, PCPC: Peadiatric Cerebral performance category, POPC: Paediatric Overall Performance Category, WOCN: Wound and Ostomy Care Nurse. SB: Skin Breakdown, PU: Pressure Ulcer, RF: Risk Factor.

Appendix 1.4: Summary of the Paediatrics' Incidence Studies

Appendix 1.5: Risk factors of PU in paediatric literature

Study	Risk factors/ Characteristics	Study Design	Population	Remarks
1- Neidig et al. (1989)	- Age of 36 months and younger. - Ventricular septal defect diagnosis. - Prolonged intubation for more than 7 days. - PICU length of stay longer than 8 days.	Retrospective Charts Review.	Children and neonates who survived an open heart surgery in PICU.	- Identifying predictors of occipital PU only. - Small sample size (n= 59). - $P < 0.05$. - Predictors were identified based on univariate analysis only. - Retrospective.
2- Zollo et al. (1996)	- Based on univariate analysis: older age, female gender, white race, had surgery, longer PICU length of stay, higher PRISM* score, had oedema, higher POPC* median, on MV*, longer length on intubation, longer length receiving neuromuscular blockers, vasopressors, and benzodiazepam. - Based on multivariate: white race and the PRISM score.	Prospective case control study.	Patients admitted to PICU.	- $P \leq 0.05$. - Used both univariate and multivariate analyses.
3- Waterlow (1997)	- Risk of PU result from extrinsic factors such as friction, shear, pressure, and moisture. - PU- patients were more with splints, casts, and lines or tubes, had severe medical condition, or prolonged surgery.	Multicenter prospective incidence study.	All children aged from neonates up to 16 years old.	- It was a descriptive, no inferential statics were used.

4- Huffines and logsdon (1997)	- PU patients' characteristics' were: younger gestational age, lower body weight. - General physical condition, activity, and nutrition were more predictive and reliable indicators of skin breakdown in this population.	Descriptive pilot study.	NICU patients.	- It was a descriptive. - Identified characteristics were not tested statistically. - Some risk factors were sub- items of the NSRAS, which based on sensitivity, specificity, and reliability measures.
5- Willock et al. (2000)	- PU patients characteristics' for both studies: occipital ulcers occurs mostly in children less than one year old, none of PU- patients were on normal diet for age, vast majority had impaired mobility, and more than half had reduced consciousness. - other factors founded in PU patients were; abnormal skin condition, over- or under- weight, unstable hemodynamic, inappropriate self care abilities for age, continence, and dehydration or oedema.	-One prospective incidence study over one month. - One day prevalence study.	- Incidence study in PICU, neurosurgical, and orthopaedic wards. - Prevalence study in paediatric hospital	- Small sample size (of incidence study, n= 82. of prevalence, n= 183). - Data was mixed of the two studies. - It was descriptive, no inferential statics were used.
6- Baldwin (2002)	- PU- patients' characteristics': majority were those with chronic disease or terminally ill (75%), 25% had suffered accidental injuries, 47% of ulcers affected children younger than 10 years old. - Sedation, hypotension, sepsis, head and spinal cord injuries, traction devices, and end- stage diseases were also mentioned, but without any given details. Spina- bifida was the single factor that was reported specifically for paediatrics.	Mail survey.	Children aged from birth up to 21 years old.	- Low response rate (25%). - No direct patient skin assessment. - It was a descriptive, no inferential statics were used. - No details about given contributing factors; number, percentage, and others. - Characteristics were mixed of data from incidence and prevalence studies.
7- Murdoch (2002)	Children with PU characteristics': were critically ill, severely hypoxic, and cardiovascular instable, with maximum inotropic support, and one was on spinal board for more than 36 hours.	Retrospective charts audit, followed by another prospective audit following an application of specific type of mattresses.	Patients admitted to PICU.	- Descriptive nature, no statistical tests used to infer relation between identified characteristics and PU occurrence in this sample. - It was narrative paper, with the audit only to test the application of new type of special mattress.
8- Curley and Quigley (2003)	- Based on simple logistic regression: younger age, use of MV, longer length on MV, use of HFOV*, use of chemical paralysis, or vasopressors, higher Ramsay score, use of TPN*, and MAP* ≤ 50 mm Hg. - Based on multiple logistic regression analysis: use of MV, higher Ramsay score, MAP* ≤ 50 mm Hg and lower Braden Q score.	Multisite prospective cohort study	Patients admitted to PICU.	- Limited to a specific age range of children (21 days- 8 years). - Used both univariate and multivariate analyses. - accounted for category I+ PUs. - $P < 0.05$.
9- McLane et al. (2004)	Children with PU characteristics': were critically ill (72%), intubated, immobile, younger than 3 months old (26%) and with longer hospital length of stay (1-2 weeks).	Multisite descriptive cross- sectional prevalence survey	All children and neonates up to 17 years old.	- Large sample size (n= 1064). - It was a descriptive study, no statistical tests used to infer relation between identified characteristics and PU

				occurrence in this sample.
10- McCord et al. (2004)	Risk factors: presence of oedema, length of stay in PICU > 96 hours, increased PEEP level, not turning patients, or turning with low air loss bed, and weight loss. - Factors which had 0.002 < P < 0.05 were: head oedema, intubation, Braden scale < 16, absence of nutrition, use of sedatives, or vasopressors, and not turning patients until 12 hours of admission.	Case control study	Patients admitted to PICU.	- P < 0.002. - used only univariate analysis to infer relation between variables. - Associated factors with PU occurrence with a P value of < 0.05 and > 0.002 were excluded.
11- Samaniego (2004)	Identified risk factors were: having insensate areas, high activity, immobility and paralysis.	Retrospective chart audit	Orthopaedics	- Retrospective exploratory, no inferential statics were used. - Small sample size (n= 50). - Findings are limited to this particular population of children.
12- Willock et al. (2005)	PU- patients characteristics': most had reduced mobility, while almost half completely immobile, had low serum albumin level (< 35g/dl), pain, low self care abilities, and below normal diet.	Multicenter incidence survey.	All children aged from 0- 18 years old.	- Descriptive study. - No mention of used statistical tests. - Small sample size (n= 54).
13- Dixon and Ratliff (2005)	- PU- patients' characteristics': critically ill, sedated, hypotensive, mechanically ventilated, immobile, as well as, weight loss, oedema, and prolonged hospital length of stay.	Two point prevalence surveys in one institution with one year in-between.	Children aged from birth up to 21 years old.	- It was a descriptive, no inferential statics were used. - No details about given contributing factors; number, percentage, and others.
14- Suddaby et al. (2005)	- By multivariate analysis: PU- patients were younger, smaller, lower Starkid scale score, had more frequent episodes of diarrhoea, and more medical devices.	Five quarterly prevalence surveys over 15 month's period.	- Children in PICU, medical-surgical, oncology, and adolescent units. - Neonates were excluded from these surveys.	- It is a cross- sectional study. - Multivariate analysis was used. - P≤ 0.05.
15- Gordon (2006)	Nine risk factors: total body surface area burned, number of splints, increased prominence of bones, prior or existed PU, MAP < 60 mm hg for past 24 hours, immobility, unburned area exposed to wetness, incontinence, and calories intake.	Modified Delphi technique by 15 burn experts.	Burn patients	- Risk factors were decided by an expert panel, no empirical evidence was achieved.
16- Schindler et al. (2007)	Identified risk factors were: - By univariate: younger in age (≤ 2 years), had longer stay (≥ 4 days), with respiratory illnesses, need MV, and high PRISM score. - By multivariate: young age (≤ 2 years), had longer stay (≥ 4 days).	Retrospective incidence study over 15- week's period.	PICU children and neonates.	- P < 0.05. - Used both univariate and multivariate analyses. - depended on retrospective data to infer association between variables.

17- Willock et al. (2007)	Risk factors were: child is difficult to position, had anaemia, equipment pressing or rubbing against skin, reduced mobility for age, prolonged surgery, and persistent pyrexia	Combination of two incidence and prevalence surveys with multicenter survey.	All children aged from birth up to less than 18 years old.	- Risk factors based on univariate analysis. - P< 0.01. - Data and sample were obtained from combining two previous studies of the same author (Willock et al. 2000, and Willock et al. 2005) to develop paediatric risk scale.
18- Schluer et al. (2009)	- PU- patients had longer length of stay than did the PU- free patients. - Majority of ulcers were device- related. - Risk factors were: the Braden score, institution, and wards.	Multisite point prevalence study.	Children aged from 0- 18 years.	- It is a cross- sectional study. - Small sample size (n= 155). - Used univariate and multivariate analyses. - P < 0.05.
19- Fujii et al. (2010)	- Based on Univariate analysis: birth weight, skin texture, incubator temperature and humidity, support surface, limited number of position changes, and the use of ETT. - Based on multivariate analysis: immature skin texture, and ETT intubation.	Multisite prospective cohort study.	Neonates nursed in incubators in the NICU	- Small sample size (n= 81). - P < 0.05. - No details mentioned about predictors based on univariate analysis.
20- Manning and Curley (2012)	Risk factors of occipital PU were: being critically ill, younger than one year old, require high risk therapies and medical devices, such as; sedation, vasopressors, MV, neuromuscular blockers, HFOV, and ECMO	Retrospective chart review	Children in acute care settings	- It is a short paper. - No mention of the used statistical tests. - Small sample size (n= 62).

* ETT: Endotracheal Tube, PRISM: Paediatric Risk Score of Mortality, POPC: Paediatric Overall Performance Category, PICU: Paediatric Intensive Care Unit, NICU: Neonatal Intensive Care Unit, MV: Mechanical Ventilation, HFOV: High Frequency Oscillatory Ventilation, TPN: Total Parenteral Nutrition, MAP: Mean Arterial Pressure, ECMO: Extra Corporeal Membrane Oxygenation.

Appendix 1.6: Summary of all identified paediatrics' RASs

RAS name/ year of development	Originality	Sub-items	Age group	Modifications	Reliability and validity	Paediatric population	Scoring system	notes
1- Waterlow 1998	It is a modification of the adult Waterlow card.	Five questions related to the child, if have: sever physical disabilities, head injury, malnourished, severely ill, if there any skin damage or bruising.	Neonates to 16 yrs	- Some modifications to reflect the paediatric characteristics', e.g.: 'skin type' category has included 'nappy rash'. - Spaces added for additional information such as position, no. Of sores and any action taken.				
2- Cockett 1998	Established based on literature review.	Ten items: weight, mobility, skin condition, diet, sedation, hemodynamic status, respiratory status, incontinence, GCS and other special considerations.				PICU	Risk score ranges from (2- 36). Two represents the lowest risk score and 36 the highest risk.	Each item has sub-items ranges from 3-5, with scores 0, 1, 2, 3, or 5. With 0-1 as the lowest risk, while 2, 3, or 5 as the highest.
3- Pickersgill 1997	Combined criteria from Medley' & Waterlow' score charts.	Six items: Build & weight for height, appetite, skin condition, mobility, elimination, and drugs.					- Risk score ranges from 0-18, As follow: - Low risk (0-5). - Medium risk (6-10). - High risk (11 or more).	- Each item has 3-6 sub-items, with scores range 0-3. - Zero is the lowest score & 3 the highest for each.

4- Bedi 1993	Based on the adult' Waterlow Card (1985).	- Include 11 items: weight, continence, skin types, mobility, appetite, age, general assessment, special risks, neurological deficit, major surgery/ trauma, and medications. - The scale has a special space for wound swaps, and specimens' chr.chs. - A full description of the wounds, including: no., exudates, odour, wound margin and others is also included.	Neonates up to 15 yrs.	- Developed in 4 stages, each lasted 6 months. - The basic format and - Headings of the Waterlow card was retained; but contents were adapted as to fit paediatrics. - A diagram to outline sores/ wounds was added to the chart. - Diarrhoea was added under the medications heading, and allergy/ marks were added to skin type. - Four additions to appetite were made such as FTT, and inclusion of 'open chest wounds' scoring 5 for post operative assessment. - Special risks were completely changed, neurologic deficit with score 5 was added, and the scoring for major surgery was increased		Paediatric ' unit; especially cardiac.	- Any child scores 10+ is at risk, 15+ high risks, and 20+ very high risk. - scores ranges from 0 to 8, with 8 scores for the malnutrition, and 0 scores for average or asymptomatic.	- Assessment done on admission, 1st day post op., and every 3ed day.
5- Braden Q (Quigley & Curley) 1996	Modifications of the adult Braden RAS	Seven items: mobility, activity, sensory perception, nutrition, moisture, friction and shear, tissue perfusion and oxygenation.	- From 21 days up to 8 yrs old.	- The subscale tissue perfusion and oxygenation was added. - All subscales have the same range of scores (1-4). - Wording changes to be applicable for the child' developmental level.	Validity & reliability was tested in one study over 322 child (age 21 days- 8yrs) in 3 PICUs. On a cut-off score of 16, sensitivity was 88%, specificity 58%. AUC was found 0.64.		- Sixteen is the cut-off score of risk. Lowest score is 7 indicating the highest risk. The highest score is 28 indicating no risk.	
6- NSRAS (Huffines & Lodgson) 1997	Based on the adult Braden scale	Six items: physical condition, mental state, nutrition, mobility, activity and moisture.	Neonates	- Physical condition is based on neonates' gestational age. - Friction and shear was deleted.	Validity & reliability was tested over 32 neonates in NICU, reliability was high for 3 subscales	Neonates, NICU.	-Each sub-scale was scored from a range of 1- 4. One is the lowest risk and score 4 is the highest. The total score ranges from 6 up to 24,	- Predictive validity of the modified scale (3 sub items: (physical condition, nutrition, mental state) was

					(physical condition, nutrition, mental state) on day 14. While the other 3 subscales were very poor.		with lowest score indicating less risk and vice versa.	conducted with a cut-off score of 5. Shown 83% sensitivity and 81% specificity.
7- The Neonatal/ Infant Braden Q RAS. (McLane et al.) 2004	Modification of the Braden Q RAS	Eight items: general physical condition, mobility, activity, sensory perception, nutrition, moisture, friction and shear, tissue perfusion and oxygenation.	Children younger than 1 year old.	Adding more descriptors for each sub-scale that fits the neonates' unique characteristics'. Also, adding a new gestational age category to target the premature infants.	Content validity was established by experience paediatric nurses & paediatric nutritionist.	NICU, infants in care units.	- The lowest score is 8 indicating the highest risk. The highest score is 29 indicating no risk. - Babies with GA >38 score 4, (33-38) scores 3, (28-33) score 2, and 1 for < 28wks.	
8- Garvin 1997		Four categories: (mobility, sensory perception, nutrition, and moisture)	No specific age group mentioned .		- One cross sectional study has compared the predictive validity of Garvin with 2 other scales (Braden Q, Glamorgan) founded that: two of the four sub-scales were significant (mobility & sensory perception). - Using logistic regression two sub-scores were significant (mobility & moisture). The AUC was 64%.		- Four categories with range of scores from 1 (no risk) to 4 (high risk). Each range of total score has different intervention category as: score of 4-5 none, 6-7 level I, 8-12 level II, 13-16 level III intervention.	
9- Pattold's scoring system (Olding & Patterson) 1998		Eight areas: cardiovascular, temperature, respiratory, mobility, nutrition, continence, skin condition, and weight status.	No specific age group mentioned			Children in critical care units	- Eight categories with range of scores from 1 to 3. Total scores classify risk as: - Low (8-14), medium (15-20), high (>20).	Further aspects had been added to the scale which are action taken as prevention and equipment that had been used. Any

								developed ulcer is documented according to its site and grade.
10- the Glamorgan RAS (Willock et al.) 2007	Made of statistical analysis of patients' data	Nine areas: mobility, equipment pressing, incontinence, nutrition, anaemia, pyrexia, tissue perfusion, albumin level, and weight.	All children age from 0 to <18 yrs.		- Based on the risk score 10; the scale was 100% sensitive. But, 50.2% specific. - The urea under the curve was: 0.912 (high predictive validity). - Inter-rater reliability was established between the researcher and 13 paediatric nurses; there was a 100% agreement in eight out of nine of its Sub-items. - Inadequate nutrition was the only sub-item with 93% agreement with Cohen's Kappa 0.63 (*P< 0.01*).	All wards	- Nine categories with different scores according to risk level weighing. - Difficult mobility with condition deterioration has the greatest score 20, followed by unable to change position without assistance and Equipment scores 15. Other sub-items scores 1 if allocated. - Total score classify risk as follow: 10+ at risk, 15+ high risk, and 20+ as very high risk.	- An extra part is provided to show the taken actions related to risk level, a diagram to show child's site of PU, description, no., and reassessment time, and the identified outcome.
11- Barnes 2004	Based on literature review.	- It is a series of questions based on the identified RFs, these are: pressure, immobility, friction & shear, nutrition, skin condition, spasm, compromised cardiovascular condition, moisture, sensory deficit, age, prolonged surgery, casts and splints, and monitor tubes. - For Each child found to be at risk, a full assessment form	All paediatrics		None.	All paediatrics	Not mentioned	- The amendments included: adding more questions related to child's risk, adding 2 more documents; the skin assessment, and wounds care plans. - Also, a patient's information leaflet for parents to

		must be filled in. - Another part is to describe preventive actions that had been taken, and suggested interventions. Additional space is applied to record the details of skin assessment and any changes in skin integrity. Body map was added to show location of skin problem.						explain any risks was ascertained.
12- The Starkid Skin Scale (Suddaby et al.) 2005	Based on the Braden Q RAS.	- Six categories: mobility/ activity, sensory perception, moisture, friction & shear, nutrition and tissue perfusion & oxygenation.	All paediatric	- Joining activity and mobility in one category. - Bold font of the key elements of each category. - Simplifying and rewording of concepts.	- Inter-rater reliability was 0.85. The sub-item nutrition had the poorest inter-rater reliability and was the less predictive of SB. - The sensitivity was low (17.5%) but with excellent specificity (98.5%). - Mobility & sensory perception were the most predictive of SB.	All paediatric	- Each category has arrange of score from 1-4; one is the highest risk, and four is the lowest. - Total score is a range from 6- 24. - The highest the total scores the lowest the risk.	
13- The Braden Q+ P Scale. (Galvin & Curley) 2012	A modification of the Braden Q RAS.	- Includes 5 major elements (intensity and duration of pressure, tolerance of kin and support surfaces, any device attached to skin, post-procedure concerns, and post-procedure assessment). - Each element has sub- items. Each sub-item has risk factors and suggested interventions.	Cardiac OR and main OR paediatric	- Adding new elements like device attached to patients during OR. - Eliminating sub-items like activity. - Adding a suggested preventive intervention for each risk factor in the tool.	none	Cardiac OR and main OR paediatric	- Yes/ No scoring system for each risk factor. - How scores would show risk is not clear.	

FTT: Failure To Thrive, Ch.Ch: Characteristics, OR: Operation Room, NSRAS: Neonatal Skin Risk Assessment Scale.

Appendix 1.7: Classification of PU according the EPUAP and NPUAP (Joint guidelines)

Grade	Short description	Definition
Category/Stage I	Non-blanchable erythema	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.
Category/Stage II:	Partial thickness	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or sero-sanginous filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising*. This category should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation. *Bruising indicates deep tissue injury.
Category/Stage III	Full thickness skin loss	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are *not* exposed. Slough may be present but does not obscure the depth of tissue loss. *May* include undermining and tunneling. The depth of a Category/Stage III PU varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III PUs. Bone/tendon is not visible or directly palpable.
Category/Stage IV	Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often includes undermining and tunneling.The depth of a Category/Stage IV PU varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

Additional Categories/Stages for the USA		
Unstageable/ Unclassified	Full thickness skin or tissue loss – depth unknown	Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.
Suspected Deep Tissue Injury	depth unknown	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or *shear.* The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Appendix 1.8: Terminology and definitions of the Glamorgan Risk Assessment Scale

The Glamorgan Risk Assessment Scale	
Terms/ Categories	**Definition**
Mobility	Has four major categories; - Child can move as any healthy child in his/her age (scores 0). e.g.: Eight months old baby who can crawl but can't walk. - Child can move body purposefully but with some restriction and reduced for age (score 10). e.g.: A healthy child but in traction. - Child can't move self without assistance, or his movement is not purposeful (score 15). e.g.: Semiconscious patient following an operation. - Child can't be moved without a great deterioration on his/ her health condition (score 20). e.g.: Ventilated patient who become severely hypoxic with positioning. This term includes the child ability to ambulate, move body position, or any physical activity.
Equipments	Includes any equipment, hard surfaces, or objects that is pressing or rubbing on the child skin for long periods that may cause skin damage (score 15). e.g.: ECG electrodes, ID bands, linens folds.
Significant Anaemia	If Haemoglobin level is below 9g/ dl (score 1). If above 9g/dl or none measured (score 0).
Persistent Pyrexia	If temperature >38.0ºC for more than 4 hours (score 1), if less than 38 or not persisted for 4hours or more (score 0).
Poor Peripheral Perfusion	If the child has cold mottled skin in warm environment, or the capillary refill was > 2 seconds (score 1).
Inadequate Nutrition	Child who are malnourished, but not including those who are NPO before surgery (score 1).
Low Serum Albumin	Serum Albumin level less than 35 g/ dl (score 1), if higher or not measured (score 0).
Weight less than 10^{th} centile	Calculated based on child age to weight plots (score 1 if less than 10^{th} centile). See Appendix (XXX) for the plots charts.
Incontinence	If not appropriate for the child age (score 1). e.g.: infant who is urinating on nappies day and night is normal for the age.

Appendix 1.9: Terminology and Definitions of the Braden Q Risk assessment Scale

The Braden Q Risk Assessment Scale	
Terms/ Categories	**Definition**
Mobility	The child is independence in controlling and moving his/her body position. It includes four categories; completely immobile, very limited, slightly limited, and no limitations. Nurses/ parents assistance is not counted if existed.
Activity	The child current physical activity or ability to ambulate, while considering the developmental milestones for each child age. It includes four categories; bed fast, chair fast, occasionally walks, and frequently walks.
Sensory Perception	The child ability to respond to pressure o discomfort appropriately based on the developmental level. It's a measure of the child consciousness, sensation, or both. It includes four categories; completely limited, very limited, slightly limited, and no limitations.
Moisture	The child degree of moist over his/ her bony prominence may be a result of urine, faeces, drainage, perspiration and others. It is include four categories; constantly moist, very moist, occasionally moist, and rarely moist.
Friction and Shear	The child skin moves against support surfaces, or the skin and an adjacent bony prominence is sliding over each other. This would be affected by the nurse ability to left patient, the child ability to control body, or if the child is sliding down in the bed, also any contracture, or agitation. It includes four categories; significant problem, problem, potential problem, and no apparent problem.
Nutrition	The child nutritional intake pattern, any weight changes, enteral feedings or the serum albumin level. It includes four levels; very poor, inadequate, adequate, and excellent.
Peripheral Perfusion and Oxygenation	The child perfusion and oxygenation status, including serum haemoglobin level, blood pressure, serum PH, capillary refill, and oxygen saturation and others. It includes; extremely compromised, compromised, adequate, and excellent.

Appendix 1.10: The Glamorgan Pressure Ulcer Risk Assessment Scale

Risk Factor *(If data such as serum albumin or haemoglobin is not available, write NK – not known and score 0)*	**Score**	**Assessment findings**
Child cannot be moved without great difficulty or deterioration in condition / under general anaesthetic >2 hours	20	
Unable to change his/her position without assistance /cannot control body movement	15	
Some mobility, but reduced for age	10	
Normal mobility for age	0	
Equipment / objects / hard surface pressing or rubbing on skin	15	
Significant anaemia (Hb <9g/dl)	1	
Persistent pyrexia (temperature > 38.0ºC for more than 4 hours)	1	
Poor peripheral perfusion (cold extremities/ capillary refill > 2 seconds / cool mottled skin)	1	
Inadequate nutrition (Consult dietician if in doubt)	1	
Low serum albumin (< 3.5g/l)	1	
Incontinence (inappropriate for age)	1	
Total score		
Action Taken (Yes or no – document in child's nursing record)		
Signature		

Risk score	Category	Suggested action
0	Not at risk	Continue to reassess daily and every time condition changes.
10+	At risk	Inspect skin at least twice a day. Relieve pressure by helping/ encouraging the child to move at least every 2 hours. Use a size and weight appropriate pressure redistribution surface for sitting on &/or sleeping on if necessary.
15+	High risk	Inspect skin with each repositioning. Reposition child / equipment/ devices at least every 2 hours. Relieve pressure before any skin discolouration develops. Use a size and weight appropriate pressure redistribution surface for sitting on &/or sleeping on.
20+	Very high risk	Inspect skin at least hourly if condition allows. Move or turn if possible, before skin becomes discoloured (refer to EUPAP grade 1). Ensure equipment / objects are not pressing on the skin. Consider using specialised pressure relieving equipment. Refer to local guidelines/protocol if available, if not contact / refer to TVN.

Appendix 1.11: The Braden Q Risk Assessment Scale

Intensity and Duration of Pressure					
Mobility	**1. Completely immobile:**	**2. Very limited:**	**3. Slightly limited:**	**4. No limitations:**	**Score**
The ability to changes and control body position	Does not make even slight changes in body or extremity position without assistance	Makes occasional slight changes in body or extremity position but unable to completely turn self independently	Makes frequent though slight changes in body or extremity position independently	Makes major and frequent changes in position without assistance	
Activity	**1. Bedfast:**	**2. Chair fast:**	**3. Walks occasionally:**	**4. All patients too young to ambulate or walks frequently:**	
The degree of physical activity	Confined to bed	Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted in to chair or wheelchair.	Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.	
Sensory perception	**1. Completely limited:**	**2. Very limited:**	**3. Slightly limited:**	**4. No impairment:**	
The ability to respond in a developmentally appropriate way to pressure-related discomfort	Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation or limited ability to feel pain over most of the body surface	Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness or has sensory impairment which limits the ability to feel pain or discomfort over ½ of body	Responds to verbal commands, but cannot always communicate discomfort or need to be turned or has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities	Responds to verbal commands. Has no sensory deficit, which limits ability to feel or communicate pain or discomfort	
Tolerance of the Skin and Supporting Structure					
Moisture	**1. Constantly moist:**	**2. Very moist:**	**3. Occasionally moist:**	**4. Rarely moist:**	
Degree to which skin is exposed to moisture	Skin is kept moist almost constantly by perspiration, urine, drainage, etc. Dampness is detected every time patient is moved or turned	Skin is often, but not always moist. Linen must be changed at least every 8 hours	Skin is occasionally moist, requiring linen change every 12 hours	Skin is usually dry, routine diaper changes, linen only requires changing every 24 hours	
Friction and Shear	**1. Significant problem:**	**2. Problem:**	**3. Potential problem:**	**4. No apparent problem:**	
Friction: occurs when skin moves against support surfaces *Shear*: occurs when skin and adjacent bony surface slide across	Spasticity, contracture, itching, or agitation leads to almost constant thrashing and friction	Requires moderate to maximum assistance in moving. Complete lifting without sliding against	Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair,	Able to completely lift patient during a position change. Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move.	

one another		sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance.	restraints, or other devices. Maintains relative good position in chair or bed most of the time but occasionally slides down.	Maintains good position in bed or chair at all times.	
Nutrition	**1 Very poor:**	**2. Inadequate:**	**3. Adequate:**	**4. Excellent:**	
Usual food intake pattern	NPO and/or maintained on clear liquids, or IVs for more than 5 days or albumin less than 2.5 mg/dl or never eats a complete meal. Rarely eats more than ½ of any food offered. Protein intake includes only 2 servings of meat or dairy products per day. Takes fluids poorly. Does not take a liquid dietary supplement	Is on liquid diet or tube feedings/TPN which provides inadequate calories and minerals for age or albumin less than 3 mg/dl or rarely eats a complete meal and generally eats only ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement.	Is on tube feedings or TPN, which provide adequate calories and minerals for age or eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally will refuse a meal, but will usually take a supplement if offered.	Is on a normal diet providing adequate calories for age. For example, eats/drinks most of every meal/feeding. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation	
Tissue perfusion and oxygenation	**1. Extremely compromised:**	**2. Compromised:**	**3. Adequate:**	**4. Excellent:**	
	Hypotensive (MAP less than 50mmhg: less than in a newborn) or the patient does not physiologically tolerate position changes	Normotensive; oxygen saturation may be less than 95 percent or hemoglobin may be less than 10 mg/dl or capillary refill may be greater than 2 seconds; Serum pH is less than 7.40	Normotensive; oxygen saturation may be less than 95 percent or hemoglobin may be less than 10 mg/dl or capillary refill may be greater than 2 seconds; Serum pH is normal	Normotensive; oxygen saturation greater than 95 percent; normal hemoglobin; and capillary refill less than 2 seconds.	
Total					

Appendix 2.1: De Montfort University ethical approval

dmu.ac.uk
DE MONTFORT UNIVERSITY
LEICESTER

1st September 2010

Laila Habib Allah
PhD Candidate
c/o Dr Peter Norrie
School of Nursing & Midwifery

Dear Laila,

Re: Ethics application – PhD: Incidence and prevalence of pressure ulcer among Jordanian paediatric patients, and the validity of the Glamorgan Risk Assessment Scale (ref: 658)

I am writing regarding your application for ethical approval for a research project titled to the above project. This project has been reviewed in accordance with the Operational Procedures for De Montfort University Faculty of Health and Life Sciences Research Ethics Committee. These procedures are available from the Faculty Research and Commercial Office upon your request.

I am pleased to inform you that ethical approval has been granted by Chair's Action for your application. This will be reported at the next Faculty Research Committee, which is being held on 21st October 2010.

Should there be any amendments to the research methods or persons involved with this project you must notify the Chair of the Faculty Research Ethics Committee immediately in writing. Serious or adverse events related to the conduct of the study need to be reported immediately to your Supervisor and the Chair of this Committee.

The Faculty Research Ethics Committee should be notified by e-mail to HLSFRO@dmu.ac.uk when your research project has been completed.

Yours sincerely,

Professor Paul Whiting
Chair
Faculty of Health and Life Sciences
Research Ethics Committee

Faculty of Health and Life Sciences, The Gateway, Leicester LE1 9BH.
Tel: (0116) 255 1551 / **Fax:** (0116) 257 7135

Appendix 2.2: Ethical approval for the Jordanian university hospital- KAUH

جامعة العلوم والتكنولوجيا الأردنية
Jordan University of Science and Technology

مستشفى الملك المؤسس عبدالله الجامعي
King Abdullah University Hospital

لجنة البحث على الإنسان
Institutional Review Board

Ref.: 13/39/2011 dated in: 13/10/2011
Date: 21/11/2011

الرقم:
التاريخ: ..... هـ
الموافق: ..... م

Professor Paul Whiting,
Chair, Faculty Research Ethics Committee
Faculty of Health and life Sciences
De Montfort University

Dear Dr. Paul

In referrence to your letter, in which you confirmed that Ms. Laila Habib Allah is a Doctoral student at De Montfort University, and will be undertaking a project entitled:

" Incidence and prevalence of pressure ulcer Jordanian pediatric patients and the validity of Glamorgan risk assessment scale "

We would like to inform you that the IRB Committee has granted Ms. Laila Habib Allah the approval to conduct her proposal at King Abdullah University Hospital for the purpose mentioned above, under the following conditions:

1. Confidentiality is required while collecting data.
2. Informed consent (For the children) is required to be kept in the medical record.
3. Provide us with a final report including patient's names.
4. Provide us with the final results of the research before publishing.

Sincerely,,,

Prof. Mahmoud Al-Sheyyab
IRB Chairman

Jordan University of Science & Technology
King Abdullah University Hospital
Institutional Review Board
P.O.Box (630001 Irbid (22110) Jordan
E-mail: irb@kauh.jo

Sh.A / Committees Coordinator

Tel.: 962-2-7200600 Fax: 962-2-7095777 P.O. Box: 630001 Irbid 22110 Jordan Email: kauh"just.edu.jo

Appendix 2.3: Letter of Invitation to participants/ English Version

Research title: ***Incidence and prevalence of pressure ulcer among Jordanian paediatric patients, and the validity of The Glamorgan risk assessment scale.***

Researcher: ***Laila Habib Allah***

Invitation letter

We would like to invite you, on behalf of your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. The researcher will go through the Participant Information Sheet with you and answer any questions you have. This should take about 5-10 minutes. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to your child if you take part. Part 2 gives you more detailed information about the conduct of the study. This study is part of a research project leading to a PhD degree in Nursing from De Montfort University in England. It is a survey including all paediatric inpatients in this hospital to determine the size of the pressure ulcer problem within the paediatric population, and to determine which children are at risk. Ask us if there is anything that is not clear.

If you think your child is able to give his or her own permission, an extra form, appropriate for his/her age, can be provided to him/her, so he/she can decide personally either to participate or not.

Thank you for taking part in this study

Laila Habib Allah

Appendix 2.4: Letter of Invitation to participants/ Arabic Version

نسبة حدوث القروح الضغطية للأطفال المقيمين في أقسام العناية الحثيثة في الأردن, ومقارنة اداتين(Braden Q and Glamorgan) كفاء في قياسها

ليلى حبيب الله
جامعة ديمونت فورت
كلية العلوم الصحية والحياتية
قسم التمريض

دعوة للمشاركة في بحث

انني أدعوكم للمشاركة في هذا البحث بالنيابة عن طفلكم, قبل أن يتخذ أي منكم قرارا, نود أن نشرح له عن البحث. هذا البحث يهدف لدراسة مشكلة التقرحات الضغطية لدى الأطفال ومعرفة الأسباب التي قد ترتبط بحدوثه, سيقوم الباحث بالشرح لك أكثر بالجزئين المرفقين: الجزء الأول ورقة المعلومات, والجزء الثاني نموذج تفويض, هذا لن يستغرق أكثر من 10 دقائق.هذا البحث هو جزء من متطلبات نيل شهادة الدكتوراة من جامعة ديمونت فورت البريطانية, اذا رغبت بمعلومات أكثر رجاءا قم بسؤالنا. اذا أردت أن تخبر أحدا اخر عن البحث نحن لا نمانع.

اذا كنت ترى أن طفلك قادر على اتخاذ القرار بنفسه أخبرنا ونحن سنقدم ورق معلومات خاصة بالأطفال مناسبة لعمره ودرجة فهمه, وسيتمكن من اتخاذ القرار بنفسه.

شكرا على وقتكم وعلى اخذكم هذا الطلب بعين الاعتبار

ليلى حبيب الله

Appendix 2.5: Participants Information Sheet (**parents, guardian)** / English Version

- ***This sheet has 2 parts.***

Part 1

1.1 What is the purpose of the study?

This study concerns the problem of pressure ulcers among children, and how common these are in Jordanian hospitals. We believe it can improve our understanding of the factors that make children prone to this problem. Pressure ulcer means any sores, redness or ulcerations that can be found by the researcher during an assessment of your child's skin that could result from shearing, friction, device compression or any other conditions.

Skin assessment is an important part of children's care in hospitals, especially those who are young or immobile, because it was found that such children are at higher risk of skin damage than any other children. This problem is important because it can delay child health progress, may increase the length of stay in hospital and it may increase the child's risk of further infection and complications.

1.2 Why my child has been invited?

All children aged from birth to 18 years old currently admitted in the hospital are invited to participate.

1.3 Does my child have to take part?

No, It is up to you to decide whether your child to takes part or not. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form.

1.4 What will happen to my child if he/she takes part?

A skin assessment will take place at the child's bedside and will not take longer than 10 minutes to complete. It will focus specifically on the most common areas of this problem including sacrum, heal, hip, back of the head, ears and hands. Your child's medical record will be reviewed by the researcher to collect some data regarding age, gender, medical diagnosis and blood tests which may found significant for the study.

1.5 How long will this assessment of my child's skin take?

This skin examination will be repeated for your child on a daily basis until your Childs' discharge, or up to 8 weeks which is the length of the study. If your child is found to have a pressure ulcer at the first day no further skin assessments will be done.

1.6 What are the possible risks and/or benefits of taking part?

There are no known risks for this study and I cannot promise you with any personal benefits from your child's participation. However, the information I will get from this study will help in better understanding of this problem among children. Understanding the problem can help in minimizing its occurrence among children in the future.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

2.1 Will my child taking part in the study be kept confidential?

Your child data will not be shared with anyone. All personal information such as your child's name will be removed from the data and will be replaced with a number. A list linking the number with your child name will be kept in a secure place, separate from your child's information. If the results of the study are published, your child's name will not be used and no information that discloses your child's identity will be released or published without your specific consent to the disclosure.

2.2 What will happen if I don't want my child to carry on with the study?

You are completely free to withdraw your child from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your child will receive.

2.3 What if there is a problem?

If you encounter any problem or for complaints, please don't hesitate to contact:

- Dr. Peter Norrie (PhD supervisor)
E-mail: pnorrie@dmu.ac.uk
Charles Frears Campus De Montfort University
266 London Road,
Leicester, UK
LE2 1RQ
Tel: 0044116 201 3914
Or:
- Miss Shatha Ayoub
Research Ethics Committee Coordinator
King Abdullah University Hospital (KAUH).
Jordan. Irbid (22110)
P.O. Box 360001.

E-mail: shatha.ayoub@gmail.com
Tel: 0096227200610 ext.: 45011

2.4 What will happen to the results of the research study?
The results of this study will be available from the researcher after completion; any participant can call or E-mail the researcher for a copy of the results. In addition, if you have any questions about the research now or later, or you have any questions regarding your child rights as a research participant, please contact me on my details below.

2.5 Who is organising and funding the research?

This study is being organized by the School of Nursing and Midwifery at De Montfort University in the UK.

2.6 Who has reviewed the study?

This study had been ethically approved by the Faculty of Health and Life Science Research Ethics Committee at De Montfort University, England. The research and ethics committee of this hospital have also approved this study.

Thank you for considering taking part in this research. The researcher will contact you soon. You can ask any questions you have and let him know whether you would like to take part or not.

Further information and contact details:

In UK:
Laila Habib Allah
De Montfort University
Faculty of Health & Life Sciences
School of Nursing & Midwifery, Charles Frears Campus
Mary Seacole Research Centre
266 London Road
Leicester LE2 1RQ
United Kingdom
Email: p09050864@mymail.dmu.ac.uk
Mobile: 00447743373329

In Jordan:
Laila Habib Allah
Al-afrah street, Al- Barha, Irbid, Jordan.
Email: lailahabeeb2007@yahoo.com, Mobile: 00962777514857.

Appendix 2.6: Participants Information Sheet (**parents, guardian)** / Arabic Version

نسبة حدوث القروح الضغطية للأطفال المقيمين في أقسام العناية الحثيثة في الأردن, ومقارنة كفاءة اداتين (Braden Q and Glamorgan) في قياسها

ليلى حبيب الله
جامعة ديمونت فورت
كلية العلوم الصحية والحياتية
قسم التمريض

ورقة معلومات خاصة بالمرضى (نسخة الوالد)

هذه الورقة تتضمن جزئان 1, 2

الجزء 1

- ما الهدف من الدراسة؟
دراسة القروح الضغطية التي من الممكن ان يكون طفلكم قد تعرض لها, هذه الدراسة من شانها تحديد حجم المشكلة في الاردن للوقوف على الاسباب المؤدية لها وكيفية الوقاية او العلاج منها.

- ماهي القروح الضغطية؟
القروح الضغطية (وتعرف ايضا بالعقر او قروح الفراش) تصيب الاطفال العاجزين عن الحركة والمرضى في الفراش، تصيب عادة الجلد في اماكن فوق العظم – خاصة عند الكاحل والارداف واصابع الرجلين ومؤخرة الراس.

- ماهو سبب هذه الدراسة؟
هذه الدراسة تجرى من اجل تحديد حجم مشكلة القروح الضغطية في الاردن حيث ان هذه المعلومات غير متوفرة لذلك، وعند تحديد حجم هذه المشكلة بدقة فانه بالامكان اعطاء توصيات لاصحاب القرار من اجل رسم سياسات واضحة للحد من هذه المشكلة والتخفيف من حالات ظهورها علما بانها يمكن منعها بشكل كبير جدا. بالاضافة الى ان تكلفة علاج هذه المشكلة باهظه جدا.

- ماذا تتضمن هذه الدراسة؟
سوف يطلب منكم الباحث بالسماح له بمعاينة جلد الطفل لمعرفة ما اذا كان هنالك احمرار او تشقق في الجلد. وخصوصا في الاماكن الاكثر عرضة كما هو موضح في الصورة السابقة. سوف يطلب منكم الباحث بالسماح له بالطلاع على ملف الطفل الطبي لمعرفة ما اذا كان هناك ذكر للقروح الضغطية فيه، لن يتم نقل الملف الطبي من المكان.

- كم ستستغرق؟
سوف تستغرق هذه الدراسة من 5-10 دقائق من وقتكم، كما قد يتطلب متابعة الطفل مدة لن تزيد عن 8 اسابيع, واذا وافقتم على المشاركة في هذه الدراسة.

<u>اذا قرأت الجزء الأول وكنت مهتما بالمشاركة, الرجاء قراءة الجزء الثاني قبل اتخاذ القرار بالمشاركة:</u>

الجزء 2

- مالذي سيحدث للمعلومات؟
سوف يتم جمع المعلومات التي التي يحصل عليها منكم ومن بقية المرضى ويصار استخدامها من اجل تكوين فكرة عن حجم المشكلة وسيتم تزويد مستشفاكم بذلك، حتى يتم التعامل بشكل فاعل مع الحالات التي فيها احتمال نشوء قروح ضغطية.
سوف تساعد هذة المعلومات ايضا على تحديد مخاطر نشوء الاصابة بقروح الضغط بالضبط ، وماهي الاشياء الاساسية التي يجب عى النظام الصحي والكادر الطبي وبخاصة التمريض ان يعملوها من اجل التخفيف من هذه المشكلة.
سوف تستخدم معلوماتكم الشخصية فقط للمساعدة بتحليل المعلومات. سيتم ازالة بياناتكم الشخصية قبل اصدار اي تقرير وسوف يتم اتلافها فور الانتهاء من الدراسة.

- هل ستترتب اي مخاطر من المشاركة في هذه الدراسة؟
- ان مشاركة الطفل في هذه الدراسة لن تتدخل باي شكل من الاشكال في علاجه.
- ان مشاركة الطفل اختيارية طوعية كليا ولكم حرية تغيير رايكم في اي وقت تشاؤون.
- تعتبر خصوصياتكم وسرياتكم على راس اولويات الباحث.
- لن يتم الاحتفاظ باي معلومات من شانها ان تشير الى هوياتكم.

- ماذا أفعل اذا واجهت مشكلة؟
الرجاء لا تتردد بالتواصل مع:
د. بيتر نوري
مشرف رسالة الدكتوراة
جامعة ديمونت فورت- بريطانيا
البريد الالكتروني: pnorrie@dmu.ac.uk
شارع لندن 266

ليستر
ت: 00441162013914

أو

الانسة شذى أيوب
منسقة لجان أخلاقيات البحث
مستشفى الملك المؤسس
الأردن- اربد 22110
البريد الالكتروني:shatha.ayoub@gmail.com
ت: 009267200610 فرعي 45011

- المزيد من المعلومات؟
للحصول على اي معلومات اضافية ارجو سؤال الباحث في الايام المحددة للدراسة عن اي شئ قد يكون غير واضح، واطلبوا منه ان يشرح لكم بشل موسع.

- من ينظم البحث؟
كلية التمريض من جامعة ديمونت فورت- بريطانيا.

- من أشرف على البحث؟
لجنة أخلاقيات البحث العلمي بالمستشفى والجامعة.

للمزيد من المعلومات والتواصل:
في بريطانيا:
ليلى حبيب الله
جامعة ديمونت فورت- بريطانيا
كلية التمريض
شارع لندن 266- ليستر
البريد الالكتروني: p09050864@mymail.dmu.ac.uk
ت: 00447743373329

في الأردن:
ليلى حبيب الله
شارع الأفراح
البارحة- اربد
الأردن
البريد الالكتروني: lailahabeeb2007@yahoo.com
ت: 00962777514857

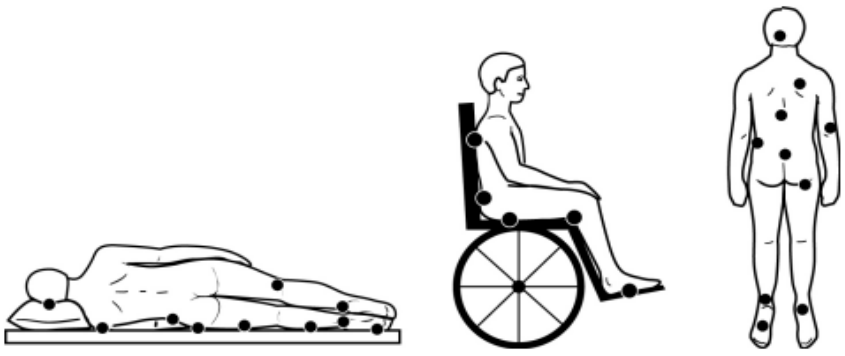
شكرا على وقتكم وعلى اخذكم هذا الطلب بعين الاعتبار

Appendix 2.7: Participants Information Sheet (**Child)** / English Version

Study title: *how often do children in Jordanian hospitals get broken and sore skin, and why?*

My name is Laila; I am from De Montfort University. We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

1. ***Why are we doing this research?***
   In our research study we want to learn more about skin problems in children. We want to know how many children in the hospital have skin problem and why.
2. ***Why have I been invited to take part?***
   All children aged from birth till 18 years old and currently admitted in the hospital will be asked to join us in the study.
3. ***Do I have to take part?***
   No, it is up to you. Taking part in the research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.
4. ***What will happen to me if I take part?***
   I want to see you every day during your stay in the hospital, I just want to check your skin is still good and no harm has happened to it. I will check it while you stay in your bed on the areas that appear in the picture below. This check-up will not take more than 10 minutes.



5. ***Are there any worries and/or benefits if I take part?***
   There are no known worries from this study. We cannot promise that the study will help you but we hope that the information we get when we finish the

research may increase our knowledge about children's skin problems. This may help other children in the hospital later on.

6. ***What happens when the research project stops?***
   No changes will happen to your medical care during the study or when it stops. Nurses and doctors will still take care of you all through your stay in the hospital.

7. ***What if there is a problem or something goes wrong?***
   If anything goes wrong you can tell your parents or if you prefer you can tell the researcher and we will work to solve the problem together.
8. ***What if I don't want to do the research anymore?***
   If you say yes and change your mind later that is OK. You can stop being in the research at any time. If you want to stop, please tell us.
9. ***Will anyone else know I'm doing this?***
   We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed.
10. ***Who has reviewed the study?***
    Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. The project has been checked by the De Montfort University Research Ethics Committee as well as the Hospital Ethics Committee.

Please talk this over with your parents before you decide whether or not to participate. Your parents have given their permission for you to take part in this study. Even though your parents said "yes," you can still decide not to do this.

Take the time you need to make your choice. Ask us any questions you have. You can ask questions at any time.

Appendix 2.8: Participants Information Sheet (**Child)** / Arabic Version

نموذج ورقة معلومات (نسخة الطفل)

عنوان البحث: كم غالبا يتعرض الطفل لتقرحات الجلد الضغطية في المستشفيات الاردنية, و لماذا؟

اسمي ليلى, أدرس في جامعة ديمونت فورت, وأنا أدعوك للمشاركة في هذا البحث. البحث يساعدنا على اكتشاف أشياء جديدة.

- لماذا نقوم بالبحث؟

لكي نعرف أكثر عن مشاكل الجلد عند الاطفال, حجم المشكلة, ولماذا تحدث.

- لماذا دعوناك للمشاركة؟

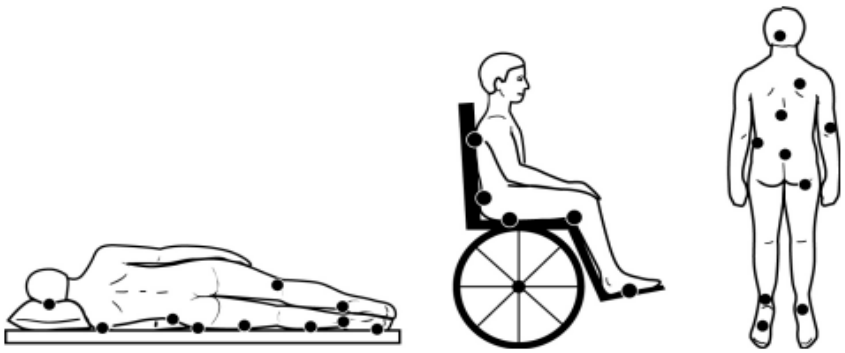
كل طفل حاليا في المستشفى وعمره من الولادة حتى 18 سنة مدعو للمشاركة.

- هل يجب أن أشارك؟

لا, هذا يرجع تماما لرغبتك, يمكنك أن توافق أو ترفض, ومهما كان اختيارك سنظل نهتم بك.

- ماذا سيحصل لي اذا شاركت في هذا البحث؟

سوف أقوم بفحص جلدك يوما بعد يوم حتى خروجك من المستشفى, لأتأكد أن لا مشاكل حدثت. الفحص سيشمل المناطق المشار اليها في الصورة, ولن تأخذ أكثر من 10 دقائق.



- هل هناك منافع أو أضرار من مشاركتي؟

لا توجد مشاكل تذكر في هكذا بحث, لكننا أيضا لا نعدك بفائدة شخصية لك, لكن نتائج البحث قد تساعد غيرك من الأطفال يوما, لأنها ستزيد فهمنا لمشاكل الجلد عند الأطفال.

- ماذا سيحصل عندما ينتهي البحث؟

سيظل الأطباء والممرضين يهتمون بك, لن يتغير غلى العناية بك شئ.

- ماذا سيحصل اذا حث أمر ما؟

يمكنك أن تخبر والديك, أو تخبرني لنحل المشكلة.

- ماذا سيحصل اذا انسحبت؟

لن يكون هناك أي عقوبات, لا بأس في ذلك, يمكنك اخبارنا متى شئت.

- هل سيعرف أحد عن مشاركتي؟

لا, هذه المعلومات تحفظ بسرية, كما أن اسمك لن يرد فيها.

- من أشرف على هذه الدراسة؟

لجنة الاشراف على أخلاقيات البحث العلمي في المستشفى وفي جامعة ديمونت فورت, للتأكد من صحة كل شئ.

الرجاء أن تناقش هذا الموضوع مع والديك, لقد وافقو على مشاركتك لكن القرار النهائي يعود لك.

Appendix 2.9: Participants Consent Form (***Parents)*** / English Version

Ward Code: *[ ]*
Patient Identification Number for study: *[ ]*

The parents/guardian should complete the whole of this sheet on behalf of his/her child.
Please tick to confirm:

I have been given written and verbal information regarding aims □
of the research and it has been explained to my satisfaction.

I have had the opportunity to consider the information, □
ask questions and have had these answered satisfactorily.

I understand that my child's participation is voluntary and □
that I am free to withdraw at any time, without giving any reason,
without my child's medical care or legal rights being affected.

I understand that the researcher will hold all information and data □
collected securely and in confidence and that all efforts will be made
to ensure that my child cannot be identified as a participant in the study.

I give permission for the researchers to hold relevant personal data □
about my child

I agree to let my child take part in the above research study □

_____ _____ _____

Name of participant parent/guardian: ***Signature***

On behalf of (Child name):

Date: _____ _____ _____

Name of researcher: ***Signature*** ***Date:***

When completed, one copy for the patient; one copy for the researcher file.

Appendix 2.10: Participants Consent Form (***Parents)***/ Arabic Version

نسبة حدوث القروح الضغطية للأطفال المقيمين في أقسام العناية الحثيثة في الأردن, ومقارنة كفاءة اداتين (Braden Q and Glamorgan) في قياسها

ليلى حبيب الله
جامعة ديمونت فورت
كلية العلوم الصحية والحياتية
قسم التمريض

نموذج تفويض للمشاركة في بحث (نسخة الوالد)

رمز القسم:
رقم المريض الافتراضي في الدراسة:

أرجو قراءة البنود التالية بدقة، ووضع اشارة (√) امام كل عبارة بالموافقة نيابة عن طفلك:

- لقد تم شرح اهداف البحث بشكل واضح وتم تقديم الشروحات الشفوية والكتابية لذلك ☐
- لقد اعطيت الفرصة الكاملة لان اسال اي سؤال وان تجاب عن اسئلتي كاملة ☐
- لقد تم التاكيد بان مشاركة طفلي في البحث اختيارية وانه يستطيع الانسحاب باي لحظة دون تقديم اسباب او ان تتاثر نوعية العناية الطبية المقدمة له ☐
- لقد تم التاكيد بان الباحث فقط لديه الحق بالاطلاع على المعلومات التي جمعت من طفلي سواء من خلال الفحص السريري او من خلال ملفه الطبي، وان كل الجهود ستبذل من اجل المحافظة على خصوصيته وسرية المعلومات ☐
- أوافق على أخذ معلومات عن حالة طفلي ☐
- بناءا على ما سبق فأنني أوافق على مشاركة طفلي بالبحث المشار اليه ☐

التاريخ	***توقيعه***	***اسم المشارك***
التاريخ	***توقيعه***	***اسم الباحث***

تحفظ نسخة للمريض ونسخة في ملفه ونسخة في ملف الباحث

Appendix 2.11: Child Assent Form / English Version

Study title: How often do children in Jordanian hospitals get broken and sore skin, and why?

Child to circle all they agree with:

Has someone else explained this study to you?	Yes/No
Do you understand what this study is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Have you had your questions answered in a way you understand?	Yes/No
Do you understand that it's OK to stop taking part at any time	Yes/No
Are you happy to take part?	Yes/No

If any answer is "No" or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below:

Your name: _____

Date: _____

The researcher who explained this project to you needs to sign too:

Print Name: _____

Sign: _____

Date: _____

Thank you for your help

Appendix 2.12: Child Assent Form / Arabic Version

نموذج مشاركة في بحث (نسخة الطفل)

عنوان البحث: كم غالبا يتعرض الطفل لتقرحات الجلد الضغطية في المستشفيات الاردنية, و لماذا؟

على الطفل أن يضع دائرة حول كل ما يوافق عليه:

- هل شرح لك أحدهم عن هذا البحث؟ **نعم \ لا**

- هل تفهم حول ماذا يدور هذا البحث؟ **نعم \ لا**

- هل سألت عن كل الأسئلة التي تريد؟ **نعم \ لا**

- هل تمت الأجابة على اسألتك بطريقة مفهومة لك؟ **نعم \ لا**

- هل تعي أنه لا بأس اذا أردت الأنسحاب في أي وقت تشاء؟ **نعم \ لا**

- هل أنت سعيد بهذه المشاركة؟ **نعم \ لا**

اذا أجبت ب " لا" على أي من الأسئلة السابقة, أو اذا كنت لا تريد المشاركة لا تكتب اسمك في الأسفل. اذا كنت تريد المشاركة قم بكتابة اسمك الأول في الأسفل:

الأسم:_____

التاريخ:_____

الباحث الذي قام بالشرح للطفل عن هذا البحث, اكتب اسمك وتوقيعك في الأسفل:

الأسم:_____

التوقيع:_____

التاريخ:_____

شكرا لمساعدتك

Appendix 3.1: Data Collection Sheet (Prevalence)

Incidence and Prevalence of Pressure Ulcer among Jordanian Paediatric patients, and comparing the Predictive Validity of Glamorgan and Braden Q Risk Assessment Scales

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(Prevalence Data collection tool)

- ***Ward data:***

  Ward: **Date:**

  No. Of admitted patients: **No. Of beds:**

- ***Patient demographical data:***

  Patient name: **Age:**

  File number: **Gender:**

  Medical diagnosis: **D.O.B:**

  Gestational age: **Weight:**

  Hospital length of stay: **On medical devices:**

  Date of admission: **Previous Hospitalization:**

- ***Pressure Ulcer existence:***

  ☐ **Yes** ☐ **No**

  If present;

No. of ulcers	Grade *I, II,III, IV (*EPUAP, 2009)	Location	Size in cm.	Acquired or home ulcer	Ulcer' persistence
(1)					
(2)					
(3)					
More than 3					

Appendix 3.2: Data Collection Sheet (Incidence and risk factors)

Incidence and prevalence of pressure ulcer among Jordanian paediatric patients, and the validity of Glamorgan risk assessment scale.

(Data Collection Tool)

A) General data

- ***Ward data:***

Ward: Date:

- ***Patient demographical data:***

Patient name: Age (on admission):
Hospital File no.: D.O.B: Gender:
Newborn gestational age: Med. Dx:
Previous hospitalizations:
Date of admission:
Weight ( ) Height ( ) BMI ( )
O2 sat. ( ) BP ( ) Temp ( ) R. R ( ) HR ( )

ICU length of stay: ( ) Hospital length of stay: ( )
Age (on discharge): ( )

Follow-up table:

	1st assess. (0)	2nd assess. (1)	3ed assess. (2)	4th assess. (3)	5th assess. (4)	6th assess. (5)	7th assess. (6)	8th assess. (7)	9th assess. (8)	10th assess. (9)	11th assess. (10)	12th assess. (11)
Date												
outcome												

If pressure ulcer detected;

No. of ulcers	1st date of Ulcer been observed	No. of follow-up skin assessment (1 ≤ No. ≥ 12)	Grade *I, II, III, IV* (EPUAP, 2009)	Location	Size in cm.	Reason for stopping follow-up (discharged, died, up to 8 weeks)
(1)						
(2)						
(3)						
More than 3						

1

Medical Devices:

Device	Yes
I.V Canula	
Nasal canula	
Face mask	
ETT/NTT	
electrodes	
I.D band	
O2 prop	
NGT/ PEG	
Cuff pressure	
Other	

D) Risk Factors

a) Lab test:

Albumin	HgB	WBC	Na	K	Urea	Creatinin	Glucose	Biliru	CRP	PH	PCO2	PO2	HCO3

b) Other:

- Reduced consciousness level: ☐ normal GCS ☐ below normal GCS
- On MV or have (respiratory diagnosis): ☐ Yes ☐ No
- Paralysis: ☐ Quadriplegia ☐ paraplegia ☐ not
- Age: ☐ Years ☐ Months
- Length of stay: ☐ ≤ 4days ☐ > 4days

No of days: .. . .

- Inotropic therapy: ☐ Yes ☐ No
- BP: ☐ Normal ☐ Hypotensive ☐ Hypertensive
- Temp: ☐ Normal ☐ Hypothermic ☐Hyperthermic

- Malignancy: ☐ Yes ☐ No
- Skin condition: ☐ intact ☐ compromised (edema, discoloration, extravasations) ☐ broken (burns, excoriated)
- Existence of infections: ☐ Yes ☐ No
- Chronic illness: ☐ Yes ☐ No
- Acidemia: ☐ Yes ☐ No
- Presence of surgical incision: ☐ Yes ☐ No
  - Length of surgery .....
- Receive blood transfusion: ☐ Yes ☐ No
  - Number of units.....
- Presence of DNR order: ☐ Yes ☐ No

Glamorgan RAS	Score	Assessment findings
Child cannot be moved without great difficulty or deterioration in condition / under general anaesthetic >2 hours	20	
Unable to change his/her position without assistance /cannot control body movement	15	
Some mobility, but reduced for age	10	
Normal mobility for age	0	
Equipment / objects / hard surface pressing or rubbing on skin	15	
Significant anaemia (Hb <9g/dl)	1	
Persistent pyrexia (temperature > 38.0ºC for more than 4 hours)	1	
Poor peripheral perfusion (cold extremities/ capillary refill > 2 seconds / cool mottled skin)	1	
Inadequate nutrition (Consult dietician if in doubt)	1	
Low serum albumin (< 3.5g/l)	1	
Incontinence (inappropriate for age)	1	
Total score		

Braden Q RAS					
Mobility	1. Completely immobile:	2. Very limited:	3. Slightly limited:	4. No limitations:	Score
Activity	1. Bedfast:	2. Chair fast:	3. Walks occasionally:	4. All patients too young to ambulate or walks frequently:	
Sensory perception	1. Completely limited:	2. Very limited:	3. Slightly limited:	4. No impairment:	
Moisture	1. Constantly moist:	2. Very moist:	3. Occasionally moist:	4. Rarely moist:	
Friction and Shear	1. Significant problem:	2. Problem:	3. Potential problem:	4. No apparent problem:	
Nutrition	1 Very poor:	2. Inadequate:	3. Adequate:	4. Excellent:	
Tissue perfusion and oxygenation	1. Extremely compromised:	2. Compromised:	3. Adequate:	4. Excellent:	

Appendix 3.3: Guidance on using the Glamorgan Scale

The Glamorgan scale was developed using statistical analysis (chi square and regression analysis) of detailed patient data from children aged 3 days to 18 years. It is therefore suitable for use with children from birth to 18 years, and may be suitable pre-term neonates.

A child's risk of developing a pressure ulcer should be assessed on admission and every time his/her condition changes – for example – a child may be admitted as a day case for a minor operation. Initially they are fully mobile, and have nothing pressing or rubbing on the skin. They may then have an intravenous cannula sited (potentially cannula pressing on the skin – score 15), and then have a general anaesthetic (immobile, cannot be moved during the operation – score 20), this child is then at risk of skin damage from the cannula pressing (unless action is taken to adequately pad it) and at risk of skin damage from lying on a hard surface without moving during the operation unless action is taken to place a pressure distributing surface between the child and the theatre table such as an air-filled mattress overlay). On return to the ward the child will have limited mobility (score 10 - a soft hospital mattress may be adequate to prevent pressure damage).

<u>Mobility</u>
Child cannot be moved without great difficulty or deterioration in condition – such as a ventilated child who does not maintain oxygen saturations if the position is changed, or who may become hypotensive in a certain position. Children with cervical spine injuries are limited in the positions they can lie in. Some children with contracture deformities are only comfortable in limited positions.
General anaesthetic – a child who is on the theatre table may not have their position changed during an operation.
Unable to change his/her position without assistance – a child may be unable to move themselves, but carers can move the child and change his/her position (this does not cause any deterioration in the child's condition).
Cannot control body movement – the child can make movements but these may not be purposeful, and the child is unable to consciously change his/her own position.
Some mobility but reduced for age – the child may be able to make purposeful movements and may have limited ability to change their own position but this is limited. For example – a child with developmental delay, or a child in traction who is able to make limited movements, or a child on bedrest.
Normal mobility for age – the child has the same ability to move as a normal healthy child of that age. For example, a 1 week old infant is able to move his/her limbs but is not able to roll over; a 1 year old is able to roll over, bottom shuffle or crawl, sit up and pull up to standing.
<u>Objects on the skin</u>
Equipment / objects / hard surface pressing or rubbing on the skin - Any object pressing or rubbing on the skin for long enough or with enough force can cause pressure damage. For example, wings of IV cannula, pulse oximeter probes, plastic namebands on young infants,

oxygen or CPAP masks, ECG electrodes, ET tubes, NG tubes, tight clothing, arm sling with knot pressing on neck, plaster casts and splints, arm pressing on cot sides.

The above risk factors are responsible for skin damage through pressure, friction or shear. If a child is fully mobile and does not have anything pressing or rubbing on the skin, they will not develop a pressure ulcer.

The risk factors below increase the child's risk of developing a pressure ulcer if the child has reduced mobility or objects pressing or rubbing on the skin, but if they occur in a mobile child with nothing pressing or rubbing on the skin will not cause a pressure ulcer to develop.

Significant anaemia (Hb <9g/dl) – if the haemoglobin has been measured during this admission and is below 9g/dl – score 1. If the haemoglobin is 9g/dl or above, or the haemoglobin is unknown, score 0.

Persistent pyrexia (temperature >38.0ºC for more than 4 hours) – score 1. If temperature is less than 38ºC, or pyrexia lasts less than 4 hours – score 0.

Poor peripheral perfusion (cold extremities / capillary refill > 2 seconds / cool mottled skin) – in a child in a warm environment (i.e. not due to low environmental temperature) – score 1.

Inadequate nutrition (discuss with a dietician if in doubt) – child who is malnourished (this does not include children who are just starved prior to surgery) – score 1. A child who has a normal nutritional intake scores 0.

Low serum albumin (<35g/dl) – score 1. If serum albumin is 35 or above, or has not been measured – score 0.

Weight less than 10th centile – score 1 - this can be calculated by plotting the child's weight and age on a growth chart. If the child is above the 10th centile score 0.

Incontinence (inappropriate for age) – score 1 – for example, a 4 year old child who needs to wear nappies during the day and night. Normal continence – score 0 – for example, a 5 year old who is dry during the day but may be occasionally incontinent during the night, a 12 month old who needs to wear nappies during the day and night. Incontinence itself does not increase risk of pressure ulcers, and any pressure ulcers may occur on parts of the body other than the nappy area. A child who is inappropriately incontinent may have physical or developmental problems that reduce their self care ability, mobility, or sensory awareness. Moisture lesions should not be confused with pressure ulcers.

Document total score, however scores for individual risk factors should be acted on. If the child scores 10 or higher, he/she is at risk of developing a pressure ulcer unless action is taken to prevent it. This action may include normal nursing care, such as positioning, frequent changes of position (document how often position is changed), lying the child on a soft hospital mattress or on an air-filled mattress overlay, changing the position of pulse oximeter probes, ensuring the child is not lying on objects in the bed such as tubing or hard toys, or encouraging mobilisation.

Suggested action is indicated in the table, however nurses should also use their own discretion and expertise, and if necessary seek advice from a wound care specialist if a high specification pressure redistributing surface is considered. Document action taken in child's records.

The diagram of the child can be used to indicate the position of any skin lesions. If lesions are near to, or may be associated with any equipment such as CPAP mask, nasogastric tube or splint, these should also be indicated. The skin lesions indicated in the diagram should be numbered so that they can be referred to in the table below the diagram. In the table the lesions can be described more fully, with the date they were first observed and the outcome.

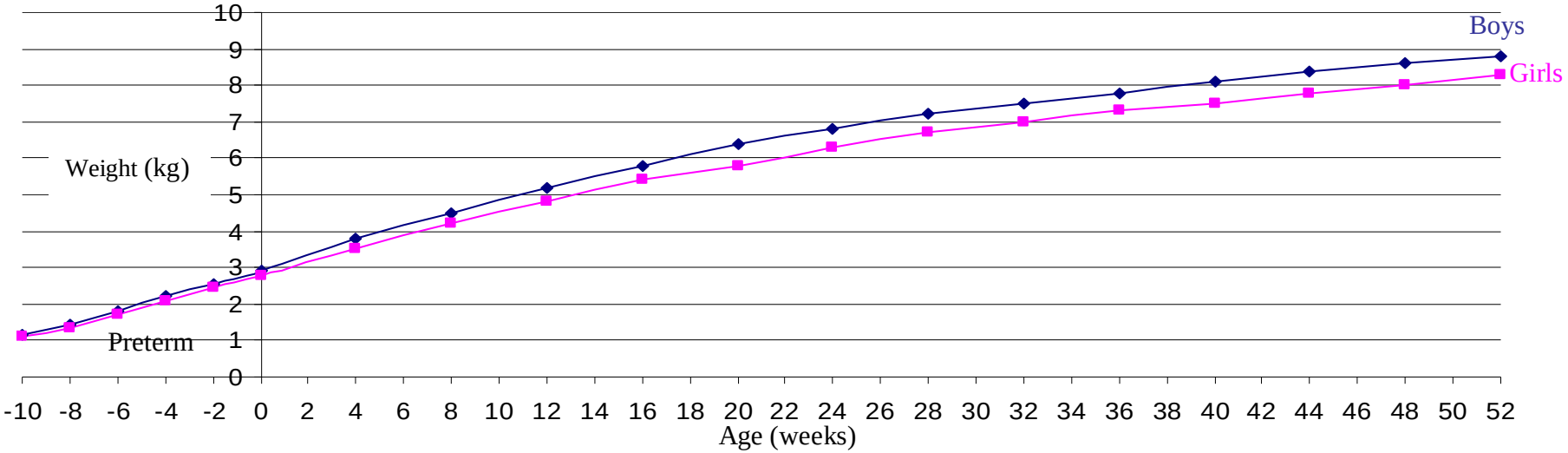
Table 1 European Pressure Ulcer Advisory Panel classification of pressure ulcers (EPUAP 2005)

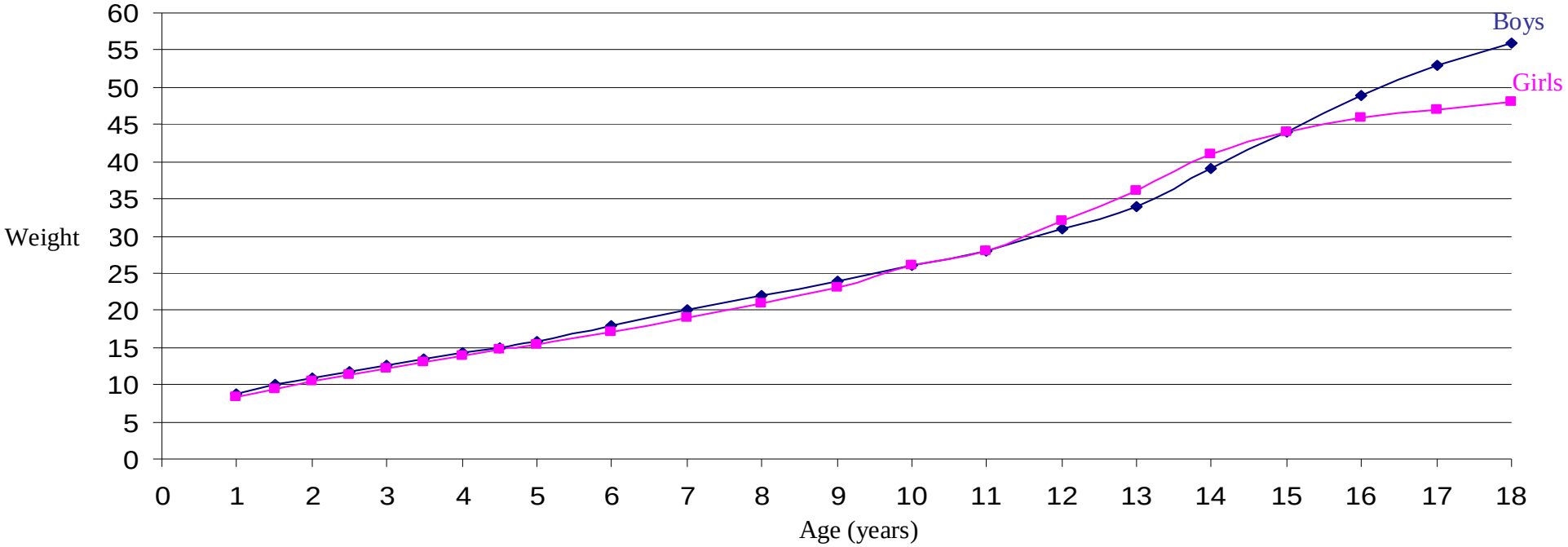
Grade	**Short description**	Definition
Grade 1	Non-blanchable erythema of intact skin	Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade 2	Abrasion or blister	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.
Grade 3	Superficial ulcer	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.
Grade 4	Deep ulcer	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.

EPUAP (2005) European Pressure Ulcer Advisory Panel, EPUAP Statement, Pressure Ulcer Classification: Differentiation Between Pressure Ulcers and Moisture Lesions http://www.epuap.org/review6_3/page6.html Accessed 08.12.06

Appendix 3.4: Centile Weight Plot

Weight below line < 10th centile





Appendix 4.1: The Braden Q ***ONLY*** significant sub-items entered in the Model

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	mobility	.371	.400	.857	1	.355	1.449
	activity	-.460	.381	1.459	1	.227	.631
	sensperception	-.606	.470	1.661	1	.197	.546
	moisture	-.776	.469	2.738	1	.098	.460
	friction	-.114	.479	.057	1	.812	.892
	tissueperfusion	-.069	.361	.036	1	.849	.934
	Constant	2.377	1.427	2.776	1	.096	10.769

a. Variable(s) entered on step 1: mobility, activity, sensperception, moisture, friction, tissueperfusion.

Appendix 4.2: The Glamorgan ***ONLY*** significant sub-items entered in the Model

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	G1	.072	.034	4.366	1	.037	1.074
	G2	1.279	292.673	.000	1	.997	3.593
	G6	-.191	1.127	.029	1	.865	.826
	Constant	-21.244	4390.090	.000	1	.996	.000

a. Variable(s) entered on step 1: G1, G2, G6.

Appendix 4.3: The Braden Q ***ALL*** significant sub-items entered in the Model

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	mobility	.273	.406	.452	1	.501	1.314
	activity	-.457	.391	1.365	1	.243	.633
	sensperception	-.558	.486	1.316	1	.251	.572
	moisture	-.823	.498	2.731	1	.098	.439
	friction	-.452	.534	.716	1	.397	.637
	nutrition	.708	.504	1.974	1	.160	2.029
	tissueperfusion	-.062	.369	.028	1	.867	.940
	Constant	1.614	1.533	1.109	1	.292	5.024

a. Variable(s) entered on step 1: mobility, activity, sensperception, moisture, friction, nutrition, tissueperfusion.

Appendix 4.4: The Glamorgan ***ALL*** significant sub-items entered in the Model

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	G1	.115	.049	5.645	1	.018	1.122
	G2	1.268	288.673	.000	1	.996	3.552
	G3	-19.294	10207.690	.000	1	.998	.000
	G4	-19.699	18415.893	.000	1	.999	.000
	G5	-18.000	9604.377	.000	1	.999	.000
	G6	.063	1.162	.003	1	.957	1.065
	G7	-1.266	1.277	.984	1	.321	.282
	G8	.301	.549	.301	1	.583	1.351
	G9	.046	.988	.002	1	.963	1.047
	Constant	-21.434	4330.098	.000	1	.996	.000

a. Variable(s) entered on step 1: G1, G2, G3, G4, G5, G6, G7, G8, G9.

THE END